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**Moving knowledge into practice: evaluating  
cross cultural applicability of the Promoting  
Action on Research Implementation in Health  
Service (PARIHS) framework**

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**A thesis submitted for the Degree of Doctor of Philosophy**

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## **Declaration**

This thesis is the work of Elizabeth Avital.

The thesis has not been submitted for a degree at another university.

## Abstract

Clinical practice guidelines are developed worldwide, at an ever increasing rate (Sandström et al., 2015) and accessed internationally without a full understanding as to whether they are applicable in cross cultural settings. Informed by a review of the literature which identified a range of theories, frameworks and models to guide knowledge translation, the Promoting Action on Research Implementation in Health Services (PARIHS) framework (Kitson et al., 1998b), was selected as a suitable framework to explore evidence based clinical guideline development work in a cross cultural context.

This research study was an exploration of the appropriateness and utility of the PARIHS framework, in the cultural translation and adaptation of an evidence based clinical practice guideline into clinical practice in the healthcare system in Malta. It also aimed to identify challenges and barriers to successful cultural translation and implementation to inform future cross cultural knowledge translation programs.

A case study using an embedded single case was used. Data collection consisted of two focus groups with multidisciplinary healthcare professionals (n=11 and n=5), eighteen semi structured interviews (n=9 pre and n=9 post) and non-participant observation of two guideline development groups. Data was analysed both inductively and deductively using Framework Analysis. Findings of the study indicate that the components of the PARIHS framework of evidence, context and facilitation are useful to guide the cultural translation and adaptation of an evidence based clinical practice guideline. In addition, a number of challenges and barriers to successful translation and potential implementation were identified; the influence of politics, culture and context, stakeholder involvement including patient involvement, and resources, both human and financial.

Overall the PARIHS framework is a useful tool to guide the cultural translation and adaptation of an evidence based clinical practice guideline. The study identified important additions to the PARIHS framework to improve its utility: expanding the use of culture in the PARIHS framework to include macro, meso and micro dimensions; the need for a definition of what context means within the PARIHS framework; the inclusion of politics as a sub element of context; the importance of resources, and acknowledging the role of the patient within the framework.

## Abbreviations

Abbreviation	Meaning
BSREC	Biomedical and Scientific Research Ethics Committee
CFIR	Consolidated Framework for Implementation Research
EBM	Evidence Based Medicine
EU	European Union
I-PARIHS	Integrated PARIHS
JUH	Jordan University Hospital
KAH	King Abdullah the Second University Hospital
KHCF	King Hussein Cancer Foundation
KTA	Knowledge to Action
MOH	Ministry of Health
NCSR	National Centre for Social Research
NGC	National Guideline Centre
NHS	National Health Service
NICE	National Institute of Health and Care Excellence
OECD	The Organisation for Economic Cooperation and Development
OMRU	Ottawa Model of Research Use
PARIHS	Promoting Action on Research Implementation in Health Services
RCP	Royal College of Physicians, London
RMS	Royal Medical Services, Jordan
UN	United Nations
UNRWA	United Nations Relief and Welfare Agency
WHO	World Health Organisation

# **1 Chapter One - Introduction**

The implementation of evidence based knowledge into practice is an area of research and practice that has been evolving over the past few decades as the production of evidence based innovations and the need for effective implementation is ever increasing. Knowledge implementation is a complex process, with many frameworks to guide it, yet there is a gap looking at the cross cultural utility of such frameworks, therefore this research seeks to evaluate this, focusing on one particular framework.

The purpose of this chapter is to outline the rationale for undertaking this study, clearly identify the research objectives and the structure of the remaining chapters.

## **1.1 Background**

The context for this study is provided by the National Guideline Centre (NGC) at the Royal College of Physicians. The Royal College of Physicians (RCP), the oldest medical college in England (founded in 1518 by a royal charter from King Henry VIII) functions not only as a membership body which “supports physicians to fulfill their potential” through a variety of activities, but to significantly and actively contribute to the design of healthcare systems and the promotion of illness prevention (Royal College of Physicians, 2017c, Royal College of Physicians, 2017b). The RCP has over 32,000 physician members worldwide, from medical trainees to retired doctors, covering 30 different medical specialties (Royal College of Physicians, 2017b, Royal College of Physicians, 2017d). Membership of the RCP reaches beyond the UK with eighteen percent being global from more than 80 countries (Royal College of Physicians, 2017a).

## **1.2 Identification of the topic**

The NGC was established in 2009 and is commissioned by the National Institute for Health and Care Excellence (NICE), to produce evidence based clinical practice guidelines, the aim of which is to improve the quality of patient care within the NHS in England and Wales. The NGC has also carried out evidence translation and utilisation in international healthcare systems looking to standardise their use of healthcare guidelines. As this international work progressed, the Promoting Action on Research Implementation in Health Services (PARIHS) framework (Kitson et al., 1998b) was identified and used to underpin the evidence translation programme. However, although the PARIHS framework was being used to guide clinical guideline development, it was evident there was a need to develop a robust

approach to considering the appropriateness and utility of cross-cultural adaptation of guidelines and guidance there was a need to examine whether guidelines developed in one country were transferable to other countries, and to examine whether the PARIHS framework was appropriate in other cultural contexts. This thesis thus reviews other frameworks to ascertain suitability and ultimately test an implementation framework for cross cultural robustness and utility.

### **1.3 Implementation of knowledge**

The implementation of evidence based knowledge as an area of research and practice continues to evolve, fuelled by the fact that on an annual basis world-wide, billions of US dollars are spent in healthcare on the generation of research and the development of evidence based innovations which are often not implemented (Chaudoir et al., 2013). Due to this, a gap has been identified referred to as the 'know-do' gap (Pablos-Mendez and Shademani, 2006) the gap between knowledge and what occurs in practice. This 'gap' or lack of utilisation of knowledge, has resulted in healthcare organisations and policy makers seeking to find ways to ensure that clinical practice is evidence based (Seers et al., 2012) and implementation strategies are suitable (Grimshaw et al., 2001). The intention being, by understanding how best to implement evidence based information into health service delivery, the aim of improving patient care can be better realised.

There are numerous theories and frameworks (discussed and outlined in Chapter 2, section 2.4), developed as a result of the drive for effective implementation of knowledge.

### **1.4 Implementation frameworks**

Implementation frameworks are varied with some being more general and focused on the whole service and others directed at where the service is delivered or who delivers it. Whatever the focus of the framework, they all distil theory and practice into key components (the number of which differ per framework) to be adhered to or considered when implementing evidence based knowledge. Following a preliminary review of the knowledge implementation literature, a variety of theories, models and frameworks were derived from those that were most frequently used and identified in the literature. Within this selection, there were some which attempt to draw together elements from supporting theories or frameworks to create service focused frameworks for knowledge implementation including; the General Theory of Implementation (May, 2013) which explains the implementation process through the identification of four main elements; capability, potential, contribution

and capacity; The Consolidated Framework for Implementation Research (Damschroder et al., 2009), which is a construct of five domains (the intervention, inner and outer setting, the individuals involved, the process of implementation) and is recommended to be used as an adjunct to other theories; a conceptual framework by Ward et al (Ward et al., 2009) which whilst they identified five common knowledge transfer processes they also identified three types of knowledge transfer processes; linear process, cyclical process, dynamic multidirectional process; the Diffusion of Innovations in Healthcare Organisations (Greenhalgh et al., 2004), which identified a larger number of components to be used for information and as motivation when considering the complexities of translating knowledge into practice.

These frameworks consolidate aspects from other frameworks and theories in an attempt to create frameworks for knowledge implementation. In doing so they illustrate the multi-layered complexity that is knowledge implementation. They highlight that it is not possible to account for all the processes involved in implementation, because they are so varied and complex. However, they do provide ideas and raise awareness of the type of factors that need to be taken into consideration.

A further four frameworks were reviewed; three of which focus on the context of knowledge translation and one which looks at the individual practitioner. The four frameworks have evolved and been refined over time and each has its own set of advantages and disadvantages, which are outlined in Chapter 2. The Ottawa Model of Research Use (OMRU) (Logan and Graham, 1998), is a two part model with six elements relating to implementation factors that are overarched by three key elements of assessment, monitoring and evaluation. The elements work together in a nonlinear fashion and it is reportedly suited to a range of healthcare professions, researchers and policy makers. The Knowledge to Action (KTA) framework (Graham et al., 2006) has the same intended audience as the OMRU and hence has a wide applicability. It is a framework of two distinct phases; knowledge creation (with four aspects of knowledge) and action (seven phase dynamic and inter-related cycle) and accounts for the whole cycle of implementation. The Stetler Model of Evidence Based Practice (Stetler et al., 2009b), is intended for individual healthcare practitioners or teams, as a guide to the application of research into practice. It is a two part model – part one consists of five sequential phases; preparation, validation, evaluation / decision making, translation/ application, evaluation (Stetler, 2010) and part two is a more in-depth explanation of the phases. It is recognised as being very complex and suggested to be used as a step by step



guide (Stetler, 2010). The final framework to be reviewed was the Promoting Action on Research Implementation in Health Services (PARIHS) framework (Kitson et al., 1998b) aimed at healthcare professionals. The PARIHS framework is a multidimensional conceptual framework with three core interacting elements: evidence, context and facilitation, each of which is broken down into sub-elements.

As in all models and frameworks, there are limitations and areas for future development. Examples of these in regards to the afore mentioned models include; the need for further evaluation and testing of models and adjunct instruments, further deconstruction of segments, more details of the process itself, clarity of versions, interaction between various elements. One limitation that applies to all is the role of the patient as this is not sufficiently addressed in any of the frameworks reviewed.

#### **1.4.1 Why was the PARIHS framework chosen?**

The PARIHS framework was identified as being suitable for this study, primarily because of its focus on high quality evidence, an environment that is receptive to change and skilled facilitation (Rycroft-Malone et al., 2004a). These are all aspects that are suitable and applicable to the knowledge translation of evidence based healthcare guidelines. The two stage process of PARIHS; stage one (evidence and context) produces data outputs which inform the intervention to be applied at stage two (facilitation) (Kitson Alison. L et al., 2008) further enhanced its suitability because it works in parallel with the development of an evidence based healthcare guideline.

### **1.5 Research gaps**

The reviewed frameworks continue to evolve in one way or another, the more they are used in practice and research gaps are beginning to be filled. However in regards to the PARIHS frameworks, some gaps still exists such as the need to ascertain whether the three elements of context, evidence and facilitation hold equal importance (Rycroft-Malone, 2010a) or even if their relative importance differs depending on the environment in which the framework is being used. Whilst the PARIHS framework has been used by researchers worldwide, from Australia (Perry et al., 2011) to Vietnam (Wallin et al., 2011) it has yet to be evaluated as a framework in a non-Western context or as a framework facilitating the development and implementation of a clinical evidence based guideline from one country into another. It is

therefore not known whether the elements outlined in the framework are transferable cross culturally.

## **1.6 Research questions**

The aim of this research is to explore the appropriateness and utility of the PARIHS framework in a cross cultural context. The following research questions were identified:

1. To explore the appropriateness and utility of the PARIHS framework, in the cultural translation and adaptation of an evidence based clinical practice guideline into clinical practice in the healthcare system in Malta<sup>1</sup>.
2. To identify the challenges and barriers to successful cultural translation and implementation to inform future cross cultural knowledge translation programmes.

## **1.7 Thesis structure**

The thesis is structured into the following chapters:

**Chapter one**, the introduction which provides a background to the research and an overview of the chapters.

**Chapter two** is the literature review. This review is divided into three sections; part one begins by charting the rise of evidence based medicine, its development and implementation. It then progresses to explain the role of knowledge translation, making sure to define the variations in terminology and definitions relating to knowledge implementation. The review moves to an evaluation of a variety of knowledge implementation theories and frameworks, concluding with the decision to use the Promoting Action on Research Implementation in Health Services (PARIHS) for the purposes of this research. Part two of the review is an exploration of the complexity of defining culture and its function within healthcare in particular organisational culture and context. The chapter continues with the identification of culture within the original knowledge implementation frameworks reviewed. Part three is an overview of the two research settings; Jordan and

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<sup>1</sup> This study began with the Royal Jordanian Medical Services, however due to unforeseen circumstances the study site had to be changed to Malta. See Chapter 2 for further explanation and background.

Malta. The intention of this chapter is to provide the reader with an understanding of the country geography, demographics and healthcare provision.

**Chapter three** is the methodology. The chapter provides an understanding as to why a particular methodology has been employed for the purpose of this research. A discussion about the different philosophical paradigms by which research can be carried out is made and concludes that the most appropriate for this study is constructivism. Qualitative case study as a methodology is further explored illustrating its suitability to this research.

**Chapter four** follows by reviewing the individual methods used in this research in turn. The methods utilised in this study are; focus group, semi structured interviews and observation. The method of data analysis (framework analysis) selected is explored using examples from the literature.

**Chapter five** is an account of the case study, how each method was used and how the data was captured including the; focus groups, interviews, guideline development and observation.

**Chapter six** presents the analysis and findings of the study in three sections. Section one is an analysis of the two focus groups that took place in Jordan and Malta, and is a commentary of key aspects that were recorded in the groups with a comparison of concepts between the two study sites. Section two presents the most salient themes identified relating to the three main elements of the PARIHS framework, identifying their function in a cross cultural setting and providing insight into how these factors interlink with one another. The final section is concerned with the findings of the participants' experience of developing the guideline and is a consideration of their view of the work undertaken.

**Chapter seven**, presents a discussion of the findings of the study focusing on the key themes that emerged. Within this discussion; key themes are linked to underpinning theory; identification is made of where further work can be carried out; original contributions to knowledge are noted; insight into the process that was undertaken and the experience of cross cultural translation is discussed; and limitations of the study and any methodological issues that arose are outlined.

**Chapter eight** is the final chapter and concludes with the key findings, identification of original contribution to knowledge and recommendations for policy, practice and research.

## **2 Chapter Two - Literature Review**

### **2.1 Introduction**

This chapter offers a background to the area of study. It commences by looking at the development of evidence based medicine, the role and use of evidence in clinical practice. An overview of the area of knowledge implementation and a definition is provided, leading to a review on a selection of knowledge implementation theories and frameworks. Assessment was made of the limitations of these frameworks, resulting in the selection of the Promoting Action on Research Implementation in Health Services (PARIHS) framework as the one most suitable for this study. Whether reference made to the role of culture in the models and frameworks reviewed is also assessed.

The second part of the review looks at culture; the breadth and complexity of it. It begins by an exploration of definitions of culture and considers possible definitions for this study. The latter part of the section focuses on organisational culture, what this means in the healthcare sphere and the relationship it has with context.

The final section of this chapter provides an overview of country characteristics and background to the countries in which this study is situated.

### **2.2 Evidence based medicine**

#### **2.2.1 The development of Evidence Based Medicine (EBM)**

The idea of medicine being underpinned by evidence, resulting in care that would be both effective and efficient, was proposed by Archie Cochrane in 1972 in his seminal book entitled 'Effectiveness and Efficiency' (Cochrane, 1972). Yet the popularity and utilisation of evidence based medicine is recognised as gaining traction in the 1990's, as concern grew regarding the utilisation of healthcare research outcomes into everyday practice and the drive to create a more efficient and effective health service (Oborn et al., 2010). The term 'evidence based medicine' was coined by Professor Gordon Guyatt in 1990, as he changed the title of the medical teaching program to insist that patient care should be delivered on the basis of evidence (Smith and Rennie, 2014). Over the following years the concept was further developed to include patient preferences and values (Smith and Rennie, 2014). The establishment of the Cochrane Collaboration in 1993 was pivotal in furthering the evidence based medicine movement (Smith and Rennie, 2014) and continues today by

producing synthesised research evidence through global collaboration and promoting evidence based clinical decision making (Cochrane, 2017b).

### **2.2.2 Definition of evidence based medicine**

To understand evidence based medicine (EBM), it is important to define it. In the 1990's (Sackett et al., 1996) defined EBM with a definition which focuses on the use of evidence to inform decision making, as it is defined as *"the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients"* (Sackett et al., 1996)(p71). Building on this and as a way of addressing the medical focus of EBM a nursing orientated definition was written to include the consideration of the expertise of nurses; *"integration of the best evidence available, nursing expertise, and the values and preferences of the individuals, families and communities who are served"* (Sigma Theta Tau International Evidence-Based Practice Task Force, 2004)(p69). Whilst the second definition expands on the types of evidence one may consider, the fundamental aim is the same, that is to say, patient care, in regards to both policy and practice should be based on the best available evidence (Pablos-Mendez and Shademani, 2006). A range of terms exist; evidence based healthcare, evidence-based practice and evidence based nursing (DiCenso et al., 1998), all of which focus on using the best available evidence to inform practice (Cochrane, 2017a). An expression that has more recently been used and which has become an expected standard of practice is evidence informed decision making (EIDM), (Yost et al., 2015). Within this review, evidence based practice will be used as the preferred term because it is understood to be a broader term which encompasses the multidisciplinary nature of healthcare provision.

### **2.2.3 Implementation of evidence**

As established, evidence based practice refers to the utilisation of evidence, to provide the best patient care. In conjunction with this is the availability of such evidence, how it is assessed and implemented into practice. Thus the implementation of evidence into practice is an area of research and practice that has been evolving over the past few decades. On an annual basis world-wide, billions of US dollars are spent in healthcare on the generation of research and the development of evidence based innovations, interventions and practices however, many are often not implemented (Chaudoir et al., 2013). To facilitate the use of evidence, countries such as the UK, US and Australia have established organisations, for example the National Institute for Health and Care

Excellence, the Agency for Healthcare Research and Quality and the National Health and Medical Research Council respectively, to produce accessible evidence e.g clinical practice guidelines. This does not however act as a guarantee that the synthesised evidence is implemented into practice, even though the use of evidence to guide decision making is being driven at all levels, for healthcare practitioners and policy (Luoto et al., 2014). In the UK efforts to integrate evidence based knowledge has primarily focused on the development and dissemination of clinical practice guidelines, but their implementation has been inconsistent (Grove et al., 2015) and hard to measure.

The lack of implementation referred to is not only a concern because of a waste of resources but, it can result in inequality and unsuitability of healthcare provision as optimum care is not provided (Graham et al., 2006) (Grimshaw et al., 2012, Grol, 2001). Alongside the failure to provide the best care available, healthcare services are incurring unnecessary costs whilst patients are ultimately experiencing a poorer quality of life (Grimshaw et al., 2012). Interventions and practices that are shown to be effective in a research environment but are not effectively translated into practice, has an impact both on healthcare providers and patients (Damschroder et al., 2009). The challenges of consistent knowledge implementation is something that occurs worldwide, yet the difficulties encountered by low and middle income countries is even more extreme where resources are scarce (Santesso and Tugwell, 2006).

For healthcare professionals to be able to make informed decisions about clinical practices, knowledge acquisition and implementation needs to be embedded in their practice (Doran and Sidani, 2007). However, there is such a plethora of evidence to implement, evidence often fails to translate into practice (Damschroder et al., 2009). To address this, clinical practice guidelines have been developed and promoted as tools for the synthesis of evidence (Shekelle et al., 2012). The following section focuses on clinical practice guidelines in greater detail.

## **2.3 Clinical practice guidelines**

### **2.3.1 Definition and purpose**

Clinical practice guidelines can be described as a distillation of evidence that is made available to healthcare practitioners with the aim of improving patient care and safety through the enhancement of clinical practice (Francke et al., 2008) (Sandström et al., 2015).

In their rawest form they can be considered as the “*foundations for efforts to improve healthcare*” (Shekelle et al., 2012) (p1), the building blocks upon which change in practice can be established and should be integral to clinical practice (Grove et al., 2015). Clinical practice guidelines are developed worldwide at an ever increasing rate (Sandström et al., 2015) and used nationally and internationally as a means of disseminating evidence based practice by transforming healthcare research into practice recommendations (van der Zijpp et al., 2016) (Lowson et al., 2015). Clinical practice based guidelines are developed to cover a variety of health topics and service delivery to include prevention, diagnosis and treatment. Not only are they considered to be a clinical aide but as they are the end product of appraised research, they help overcome barriers such as time to read the excess of clinical research papers, critical appraisal and accessibility (Grimshaw et al., 2012). Despite the inherent focus of clinical practice guidelines being for the healthcare professional community, they are also accessed by patients and can be regarded as helping to empower patients to make better informed choices (Woolf et al., 1999).

In the UK, the National Institute for Health and Care Excellence (NICE) has been developing healthcare guidance since 1999, to reduce the disparity of healthcare quality, provision and practice (Lowson et al., 2015). Whilst clinical practice guidelines are easily accessible, through online clearing houses or directly through guideline developers and providers such as NICE, this does not ensure certainty that they will be implemented (Shekelle et al., 2012), nor does it promise that they will be adhered to (van der Zijpp et al., 2016). It might therefore be said that this method of evidence dissemination has not had the health outcomes success as such investment should warrant (Rycroft-Malone et al., 2016).

### **2.3.2 Guideline implementation**

A systematic meta-review by Francke (2008) evaluated factors which impacted on guideline implementation and found that there were a number of influencing factors, including the complexity of the guideline and the characteristics of the healthcare professionals involved in the development (Francke et al., 2008). They concluded that for implementation to be effective a multifaceted implementation approach was needed, and that both the characteristics of the guideline and the professionals at whom they are targeted play important roles in successful implementation. Moreover, in addition to these factors, it has been repeatedly identified that for guideline implementation to be successful the context, including the cultural context in which guidelines are to be implemented and the influence

this has, needs to be recognised (Francke et al., 2008) (Davis and Taylor-Vaisey, 1997) (Straus et al., 2013) (Sandström et al., 2015).

### **2.3.3 Definition of knowledge implementation**

Reference has been continuously made to the implementation of guidelines, however, comprehending what is meant by implementation is crucial to understanding the process. Variations in terminology and definitions have increased as the area of implementation research has expanded (Damschroder et al., 2009). Terms and definitions are often used interchangeably such as; knowledge transfer, knowledge translation, transfer exchange, research utilisation, quality assurance, quality improvement and innovation diffusion (Ward et al., 2009) (Graham and Logan, 2006). Knowledge translation is a popularly used term from the Canadian Institutes of Health Research whereby it is defined as: *“a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically-sound application of knowledge to improve the health of Canadians, provide more effective health services and products and strengthen the healthcare system”* (Canadian Institutes of Health Research, 2017). What is illustrated by this definition is that the use of knowledge in healthcare is an interactive process covering the whole journey starting with the formation of new evidence and ending with it being used in practice (Sudsawad, 2007).

The World Health Organisation formulated a more globalised definition by defining knowledge implementation as *“the synthesis, exchange and application of knowledge by relevant stakeholders to accelerate the benefits of global and local innovation in strengthening health systems and improving people’s health”* (World Health Organisation, 2017c). Grimshaw (2012) expanded the inclusion of stakeholders by recognising the variety of stakeholders involved in the provision of care ranging from policy makers to patients themselves as they state that knowledge translation involves *“ensuring that stakeholders are aware of and use research evidence to inform their health and healthcare decision making”* (Grimshaw et al., 2012)(p2).

What these definitions illustrate is that despite the variant names or descriptions for the implementation and uptake of evidence based knowledge, the fundamental principle remains the same, that is, the purpose of knowledge translation is to move ‘knowledge into action’ (Graham and Logan, 2006). Thus the aim of the intervention is to move the research from being static into being dynamic and utilised (Tricco et al., 2016). When



referring to the complex process of facilitating the use of evidence into practice in this review, the term knowledge implementation will be used, based on the following definition which encapsulates the multifaceted nature and challenges of knowledge implementation; implementation may be defined as *“actively and systematically integrating information into place; identifying barriers to change, targeting effective communication strategies to address barriers, using administrative and educational techniques to increase effectiveness”* (Bucknall and Rycroft-Malone, 2010) (P6). As the definition of knowledge implementation has been established, the subsequent section looks at the movement of knowledge into practice and the challenges faced.

#### **2.3.4 The challenge of knowledge implementation**

The overall aim of knowledge implementation is to improve the use of research based knowledge in healthcare practice (Salter and Kothari, 2014). Over the past decade, healthcare policy and practice has become increasingly focused on the use of evidence based care to move appropriate evidence into practice as healthcare provision is not always based on the best available evidence (Oborn et al., 2010). In parallel to the desire to facilitate evidence into practice there is a frustration that research is undertaken and published but not moved into the realms of policy making or practice (Grimshaw et al., 2012) in order to improve patient care (Straus et al., 2009). This incongruence has been termed as a ‘know-do gap’ (Pablos-Mendez and Shademani, 2006), that is, the gap between knowledge and what occurs in practice. What is evident is that the existence of knowledge and the action of dissemination alone are not sufficient to effectively move knowledge into practice (Straus et al., 2009). The same difficulties associated with the movement of knowledge into practice can be found in low, middle and high income countries and across healthcare environments (Straus et al., 2009).

#### **2.3.5 Moving knowledge into practice**

The healthcare environment is a complex and diverse place, which is dynamic in nature, hence it is increasingly recognised that knowledge implementation interventions need to be sensitive to numerous aspects to ensure optimum translation such as; the identification of possible barriers and facilitators, the identification of the intended audience, the adaptation of information to suit the target audience (Grimshaw et al., 2012) and the acknowledgement of context (Rycroft-Malone et al., 2012 -a) (Estabrooks et al., 2006) (Kavanagh et al., 2007). It has further been postulated that when the target audience of

knowledge implementation is healthcare providers, the evidence should utilise systematic reviews as this assists in the globalisation of evidence (Grimshaw et al., 2012). Different theories, frameworks and models each evolving from a different theoretical background have been developed to illustrate and guide the implementation process, illustrating how implementing evidence into practice is a multidimensional, process (Rycroft-Malone, 2010b) (May, 2013). The applicability of each model, theory or framework based on this review have varying strengths and weaknesses, making them suitable for different circumstances. Examples of such models, theories and frameworks are given and discussed in detail in section 2.4 entitled Theories and Frameworks.

This 'gap' or lack of utilisation of knowledge, has resulted in healthcare organisations and policy makers seeking to find ways to ensure that clinical practice is evidence based (Seers et al., 2012). This has not only positively created an increased awareness of the importance of appropriate implementation strategies (Grimshaw et al., 2001) but has created a drive to reduce this gap (Grimshaw et al., 2012). In acknowledgement of this disparity the World Health Organisation (WHO) stated that they would be instrumental in seeking to lessen the gap and that they would support countries to do so through advancement in knowledge translation (Pablos-Mendez and Shademani, 2006). Yet knowledge implementation can be slow and is costly, with numerous influences such as who is responsible for the development of the knowledge to be implemented, trust in the people who have been involved and the culture of the receiving context, preventing effective implementation of evidence based practice (Sandström et al., 2015).

### **2.3.6 Implementation research**

As the drive for knowledge implementation has increased, as has a renewed focus on knowledge implementation research. The original conceptualisation of implementation research may be attributed to the French sociologist Gabriel Tarde in the late 1800s, who was concerned with why society adopts some innovations but not others (Tarde, 1903). However, recent growth in implementation research, in particular over the last 10 to 15 years, emulates from the same conceptual base and is driven by the need to identify the challenges, barriers and facilitators associated with the implementation of evidence based practice (Nilsen, 2015). This has occurred alongside a necessity to identify the uniqueness of each healthcare environment and the most effective means of implementing knowledge in different contexts (Kirk et al., 2016). Yet, more research needs to be carried out on why factors may work in one situation but not another (Bergström et al., 2015) as a knowledge

implementation intervention that is successful in one context is infrequently equally successful in another (Rycroft-Malone et al., 2012 -a). Furthermore, researchers have expressed concern that the processes used to implement knowledge are not achieving the desired effects (van der Zijpp et al., 2016), the provision of the best available care is not being met (Grimshaw et al., 2012), nor is there assurance that the interventions undertaken create sustainable change (Tricco et al., 2016).

### **2.3.7 Summary**

In sum, the development of implementation strategies needs to move from an approach which does not consider the diversity of an environment or context, to one which starts to accommodate these influences (Rycroft-Malone, 2010a). Research indicates that successful implementation strategies rely on a multidimensional approach, taking into consideration the intended audience, the type of knowledge to be implemented (Straus et al., 2009) and the barriers and facilitators to doing this (Wiltsey Stirman et al., 2012). Implementation theory is developed as researchers and practitioners further identify the important elements of the implementation process (May, 2013), both their individual importance and their interaction with each other. Moreover, Nilsen (2015) (Nilsen, 2015) argues it is the role of implementation research to explore these influences and continue the drive to develop a theoretical base to underpin implementation strategies.

Hence it has been established that clinical knowledge, interventions and practices are not being implemented successfully, if at all, (Chaudoir et al., 2013) for a variety of reasons. Some reasons are better understood such as the lack of an infrastructure for knowledge implementation, and others are less so, for example unsuccessful implementation where a structure exists. Acknowledgement has been made of the importance of recognising factors that aid the facilitation of knowledge implementation, with the need for further research into the identification of what these factors are. The development of this theoretical base is ongoing and it is to this that this study aims to contribute.

## 2.4 Theories and frameworks

### 2.4.1 Background

Within the arena of healthcare practice and policy, it is recognised that, it is imperative for evidence based knowledge to be implemented effectively in-order to provide optimum patient care. However, there is currently no agreement over the most efficacious way to do this (Ward et al., 2009), how to evaluate the impact of such implementation practices (Salter and Kothari, 2014) or an understanding of how implementation can be successful in one arena but not another (Kirk et al., 2016). Nor is it clear which methods are the most effective and / or in which context (Kitson Alison. L et al., 2008). Successful knowledge implementation is multidimensional, as the definitions exemplified illustrate and is reliant on a variety of factors as previously identified. To help explain and illuminate these processes and factors, numerous theories, frameworks and models have been developed (Nilsen, 2015) (May, 2013). In an attempt to distinguish between the different types of theories, models and frameworks and their roles, (Nilsen, 2015) identified three purposes of use, providing an understanding of the role that they have;

- a) A guide or description as to how to translate knowledge into practice
- b) A means for explaining or assisting the understanding of the multivariate factors that influence implementation
- c) An aid or structure to the evaluation of implementation

Ellen (2014) supports the notion that frameworks should be seen as guides to the activities or processes needed to enable the transference of knowledge into practice and identifying where the barriers and enablers are to facilitate this (Ellen et al., 2014). Whilst there needs to be an understanding of the purpose and role of theories, models and frameworks, consideration also needs to be made of the overriding principles one should consider prior to the implementation of change. These have been identified and include; acknowledgement and understanding of the complexity of the healthcare practice, the commitment of the target group, characteristics of the intervention and the importance of progress monitoring to identify whether change has occurred (Grol et al., 2007). The following will expand these principles by an evaluation of a selection of models, theories and frameworks.

### 2.4.2 Identification of theories and frameworks

The following section looks at a cross section of different types of implementation theories and frameworks. Selection of the following theories and frameworks was derived from those that were most frequently used and identified in a review of the knowledge implementation literature. The purpose of this literature review was to identify a framework suitable to facilitate the cultural translation and adaptation of an evidence based clinical practice guideline. In turn the utility and appropriateness of the framework for such a purpose will be evaluated.

### 2.4.3 Frameworks

In response to differences in terminology and in a quest to identify specific elements of successful implementation some overarching frameworks have been developed. They attempt to draw together elements from supporting theories or frameworks to create all encompassing frameworks for knowledge implementation. One such example is a **General Theory of Implementation** developed by May (May, 2013) using Normalization Process Theory as the foundations and linking it with constructs from social system theories and cognitive psychology. From this, May (2013) identified four key elements relating to the knowledge implementation process; capability, potential, contribution and capacity, at the same time acknowledging .that whilst it is possible to have both a general theory and terminology, it is not possible to account for all the processes involved in implementation as they are so variable and complex by nature (May, 2013). In the context of healthcare, process theory relates to how the organisation of an activity (how it should be planned and carried out), which aims to implement change, will be effective and how the intended audience is affected by the activity (Grol et al., 2007).

Another combined theory was developed by Damschroder et al (2009), following a comprehensive review of existing theories, models and frameworks that aim to embed research into practice; the **Consolidated Framework for Implementation Research (CFIR)** (Damschroder et al., 2009). The review resulted in the construction of five main domains; the intervention, inner and outer setting, the individuals involved, the process of implementation (Damschroder et al., 2009) which can be employed at any implementation stage (Kirk et al., 2016). The authors regard the framework as a usable guide and it is perceived as complementing other theories, in particular process theories (Damschroder et al., 2009). Subsequent to its publication as a theory, Kirk et al (2016) reviewed its use and

identified that although it had been applied in a variety of research studies and settings, they concluded that in order to aid progression of implementation science the CFIR needed to be further evaluated (Kirk et al., 2016).

A unifying conceptual model; the **Diffusion of Innovations in Healthcare Organisations** (Greenhalgh et al., 2004) was developed following a literature review, across a variety of disciplines (sociology, psychology, organisation and management, systems analysis) to ascertain how health service innovations could be disseminated in a manner which ensures sustainability. The model was created to be used as a stimulus to consider the varied and multiple complexities that impact on translating knowledge into practice. The model has nine main components, each of which has a number of detailed sub-components, which can be applied in any order and which, the authors' state, should not be used rigidly (Greenhalgh et al., 2004). The components are:

- The innovation itself, emphasising the need to make it relevant, accessible, simple and compatible with the views of the intended audience.
- Communication of the innovation. This can be achieved through a planned or unplanned process (diffusion or dissemination), using a variety of communication structures such as social networks, opinion leaders and media.
- Outer context. These are the external influences, such as whether similar organisations have done the same thing, whether there are policies that support the innovation, that impact on the organisations ability to implement the innovation and create sustainability.
- Linkage. Ensuring that during both the design stage of the innovation and the implementation stage that there are connections across the other components to assist in a systems wide approach to implementation.
- Implementation process. This is influenced by a variety of factors including system readiness, leadership and management, human and financial resources.
- Adoption and assimilation of the innovation. This is a process within which the intended user is active and will be influenced to adopt the innovation through a number of influences such as the meaning the innovation has on a personal or organisational level. Assimilation of the innovation into an organisation is a complex process that includes the adoption of the innovation.

- System readiness for innovation. Whether an organisation is open to an innovation being introduced. This is influenced by the values of the organisations, staff perception of the current situation, time and resources.
- System antecedents for innovation. The organisational context in which the innovation is to be implemented and the influence this has on its uptake and use (Greenhalgh et al., 2004).

As the nine components illustrate, it is very comprehensive, covering both the macro and micro systems involved and external influences to both, resulting in the authors recognising that it would be a challenging undertaking, to fully operationalize the framework (Greenhalgh et al., 2004). Instead they visualise it as a model to assist in the identification and understanding of the factors involved in the successful implementation of knowledge into practice (Greenhalgh et al., 2004).

A further framework to outline is one that focuses on implementation research rather than practice, created by Chaudoir et al (Chaudoir et al., 2013). They identified five factors from existing frameworks to create a multi-level framework which comprised of the following levels;

- Structural; the context in which an organisation operates.
- Organisational such as leadership effectiveness and culture,
- Provider; any individual providing care,
- Innovation, which refers to whether the innovation is regarded as being advantageous to practice and the robustness of the evidence behind it,
- Patient-level factors which focuses on the characteristics of the patient (Chaudoir et al., 2013).

Following the identification of these levels a systematic review found 62 measures that could be used to assess the five factors (there was not an equal number per factor). The result was a catalogue of measures intended for use by researchers, to assist them in appraising factors relating to implementation, e.g. organisational, provider or patient factors (Chaudoir et al., 2013).

The four frameworks outlined so far attempt to draw together elements from supporting theories or frameworks to create broad frameworks for knowledge implementation in practice and in research. These examples not only indicate that a multidimensional focus is needed at both a macro and micro level but by identifying the different aspects for

consideration, they also suggest that a single framework, may not be suitable for all situations (Ward et al., 2009). The diversity in these frameworks stems from the inclusion of different components, and they have been developed from a variety of backgrounds and influences such as psychology, behavioural change, research utilisation and organisational change (Ward et al., 2009) (Sudsawad, 2007). These frameworks are broad in their application and may be considered as lacking the finer details needed to operationalise the implementation of evidence into practice.

#### **2.4.4 Selection of frequently used models and frameworks**

Consideration of the, afore mentioned frameworks have identified the complexity of the knowledge translation process and that there are numerous factors to be considered. To extend the debate further and to provide an opportunity to incorporate other factors of importance in knowledge implementation, an additional two models and two frameworks were identified; the Ottawa Model of Research Use (OMRU) (Logan and Graham, 1998), the Stetler Model of Evidence Based Practice (Stetler et al., 2009b), the Knowledge to Action (KTA) framework (Graham et al., 2006) and the Promoting Action on Research Implementation in Health Services (PARIHS) framework (Kitson et al., 1998b). They were primarily chosen because they are; frequently referred to and utilised in the knowledge translation literature, internationally recognised and used, well established, tested and evaluated (Rycroft-Malone, 2010a). These factors have particular resonance in this study where there is a distinct focus on international usage. A framework was required in this study to guide the development of an evidence based practice guideline, thus previous use in a country other than that in which the model/ framework was developed, is important. Furthermore, as this study emphasises the influence and importance of culture, the review identifies whether the model or framework has a component or sub-component that relates to context, culture or both.

Sudsawad (2007) categorised models and frameworks looking at their different attributes (Sudsawad, 2007). Within this categorisation the OMRU, KTA and PARIHS were classified as a model and frameworks whereby the attention is on the context in which knowledge is translated and the Stetler Model as an example of a model which looks at the individual practitioner (Sudsawad, 2007). The process of categorisation of knowledge implementation models, theories and frameworks is continued by Nilsen (2015) who developed a further five categories; process models, determinant frameworks, classic theories, implementation theories and evaluation theories (Nilsen, 2015). According to these categories the KTA,



Stetler Model and the OMRU are seen as process models the function of which is to guide the process of knowledge translation, whereas the PARIHS framework is identified as a determinant framework, the function of which is to describe the multifactorial elements (both barriers and facilitators) that influence implementation (Nilsen, 2015). These distinctions have been noted because they signify the differences between the models and frameworks and indicate how one theory, model or framework does not suit all settings (Ward et al., 2009). In turn, this supports the reasoning that it is important to know the setting and population before choosing a framework (Estabrooks et al., 2006).

The following is a review of these four models and frameworks, identifying their key components, limitations and usages, to determine which one would be the most suitable to use to guide the cultural translation and adaptation of an evidence based clinical guideline in a cross cultural environment.

#### **2.4.5 The Ottawa Model of Research Use (OMRU)**

The Ottawa Model of Research Use (OMRU), was first conceptualised in 1998 (Logan and Graham, 1998). As with other models and in keeping with the developing field of knowledge implementation, the model has evolved since it was originated (Graham and Logan, 2006, Logan and Graham, 2010). The development of OMRU was twofold as it was developed as a mechanism through which the process of knowledge translation could be studied and as a practical model for multidisciplinary use to transfer healthcare knowledge into practice (Hogan, 2004) for example for the implementation of evidence based guidelines and the promotion of clinical assessment and clinical management programmes (Sandhaus et al., 2009) (Graham and Logan, 2004). It is based on theories of change (Graham and Logan, 2006), is regarded as a planned action model and is both descriptive (six elements) and prescriptive (monitoring process)(Logan and Graham, 2010). The basis of the six descriptive elements is derived from literature in areas such as physicians' behaviour, development and implementation of guidelines and research utilisation (Logan and Graham, 1998).

The authors were clear in explaining that, although these elements are linear in representation, they are not unidirectional and work influencing each other (Logan and Graham, 1998). Overarching the six key elements are what can be described as the more fixed parts of the model, the function of which is to guide facilitators in all stages of implementation of a project (Logan and Graham, 2010). They are utilised throughout the

lifecycle of the project as they are there to; identify barriers and facilitators (assess); provide direction; monitor progress and the amount of use (monitor); assess the impact of the innovation (evaluate) (Logan and Graham, 2010) (Logan and Graham, 1998). The identification of barriers to the implementation of research knowledge is a key component of the model as it is through this that the selection of appropriate intervention can be enabled (Sudsawad, 2007). This is what the OMRU was designed to do and focus on (Santesso and Tugwell, 2006) (Graham and Logan, 2006).

The model has altered over time, with changes primarily occurring in the sub elements, whilst the core elements have been maintained (even though their ‘titles’ have changed in some cases). The only structural change was the re-positioning of the *innovation element* from the bottom to the top of the diagram, as it was felt that in most projects, people start with the idea for the innovation and then the other factors are formed (Logan and Graham, 2010). As the framework evolved culture became a sub element in its own right rather than being just part of the explanation of what constituted social factors (Logan and Graham, 2010). The two iterations can be seen in Tables 1 and 2 with changes identified by underlining.

**Table 1: Representation of the original OMRU (Logan and Graham, 1998)**

<b>Assess</b>	<b>Monitor</b>		<b>Evaluate</b>
<b>Practice environment;</b> structural, social, patients, other	<b>Transfer strategies;</b> diffusion, dissemination, implementation	<b>Adoption;</b> decision, use	<b>Outcomes;</b> patient, practitioner, economic.
<b>Potential adopters;</b> knowledge, attitudes, skill			
<b>Evidence – based innovation;</b> translation process, innovation,			

**Table 2: Representation of the refined OMRU (Logan and Graham, 2010)**

<b>Assess</b> Barriers and supports	<b>Monitor</b> Process and degree of use		<b>Evaluate</b> impact
<b>Innovation;</b> <u>development</u> <u>process, innovation</u> <u>attributes</u>	<b><u>Interventions;</u></b> <u>barrier</u> <u>management,</u> <u>transfer, follow-up</u>	<b><u>Adoption; initial</u></b> <u>use, sustained use</u>	<b>Outcomes;</b> patient, practitioner, <u>system.</u>
<b>Potential adopters;</b> <u>awareness,</u> attitudes / <u>intention,</u> knowledge / skill, <u>concerns</u>			
<b>Practice</b> <b>environment;</b> structural, <u>culture</u> / social, patients, <u>economic</u>			

The intended users of the model are varied as it can be used by an organisation such as a hospital or clinical department, an individual or team (Logan and Graham, 2010). As the OMRU illustrates the processes involved in implementing research into practice, it is suitable for use by a range of professions such as healthcare providers, researchers and policy makers (Logan and Graham, 2010). This range of contextual applicability and users has resulted in application of the OMRU in different environments, for example; to identify the barriers and facilitators to guideline implementation (Fisher, 2014); as a guide to the implementation and evaluation of a pain management program developed to address variation in care provision (Sudsawad, 2007); the thematic analysis of a study to identify what influences nurses to enable use clinical symptom protocols (Stacey et al.); and of putting knowledge into action (Campbell, 2010) (Sandhaus et al., 2009). In the latter two examples, the OMRU was used alongside the Knowledge to Action (KTA) framework, illustrating how more than one model or framework can be used together.

As outlined, the OMRU framework has developed over time and has been utilised in various contexts. However, limitations of the model and its use have been identified, in particular; that further evaluation and validation of the model and (Logan and Graham, 2010) (Santesso and Tugwell, 2006) evaluation of validated instruments which support the different elements are needed (Estabrooks et al., 2006). Although the model has been used for the implementation of clinical guidelines, there is a concern that there is no reference to the quality of the evidence used in the formation of the clinical guideline, as it is not assessed but rather assumed that it is of an appropriate quality. Finally, from reviewing this model it is evident that there is no real clarity over which version of the model is in use or should be used, creating slight confusion for the user.

#### **2.4.6 The Knowledge to Action (KTA) framework**

The Knowledge to Action (KTA) framework, is a conceptual model of implementation based on planned action theories whereby planned action refers to "deliberately engineering change in groups that vary in size and settings" (Graham et al., 2006)(p20). It evolved out of a concept analysis of 31 models / frameworks (Graham et al., 2007) and was developed in an attempt to unpick the complexity of knowledge translation and by doing so, ultimately improve healthcare (Graham and Tetroe, 2010b). As with the OMRU, the intended audience is varied and not only includes healthcare stakeholders and policymakers but the public too (Sudsawad, 2007). This has resulted in it having wide applicability, in regards to both its' users and the environments in which it is to be applied.

There are two overarching components to the KTA framework; knowledge creation and action, both of which are divided into distinct phases. Firstly, knowledge creation (depicted as an inverse triangle to represent the distillation of knowledge, placed with the action cycle around it), during which knowledge is tailored, comprises of knowledge inquiry, knowledge synthesis, knowledge tools and products (Graham et al., 2006). The needs of the knowledge user can be customised throughout the different stages of knowledge creation (Sudsawad, 2007).

The second part of the framework, the action cycle, has seven phases and is a circular representation of what is necessary for the application of knowledge (Sudsawad, 2007). The authors are keen to note that although the configuration of the model is depicted in a circular fashion, the action cycle is dynamic, as the seven phases can, not only influence each other but can be influenced by the knowledge creation phase (Graham et al., 2006).

Therefore, as in the OMRU, these phases are not unidirectional with the influences of the phases flowing both ways (Sudsawad, 2007). The seven phases of the action cycle are:

- Identify problem, identify review, select knowledge
- Adapt knowledge to local context,
- Assess barriers to knowledge use,
- Select, tailor, implement interventions
- Monitor knowledge use,
- Evaluate outcomes,
- Sustain knowledge use. (Graham et al., 2006)

The emphasis on understanding the local context and the need to adapt the knowledge accordingly, is an important incorporation in the KTA framework, particularly when one considers that by acknowledging the impact of context changes are more likely to be successful (Graham and Tetroe, 2010b). In regards to adaption of knowledge to the local context, the framework refers to those implementing the knowledge judging its acceptability to the context and being aware of external influences (Graham et al., 2006). The KTA framework can be regarded as a more holistic view of knowledge translation, not only because it accounts for the whole cycle of implementation, the status of the knowledge used is not based on assumption (yet further clarity is needed as to what it is based on), it goes beyond implementation and monitors the impact of the innovation (Sudsawad, 2007). An inherent aspect of this study is the evidence used to formulate the clinical practice guideline, with emphasis on the quality of the evidence used as this is regarded as being fundamental to development.

The Canadian Institutes of Health Research have adopted the KTA framework to promote the use of research and use it to facilitate knowledge translation (Straus et al., 2009). It is regarded as providing a very clear outline of what is needed for successful knowledge implementation and is seen as a structure that can be used to plan for knowledge translation (Wilson et al., 2011). The model has been used in practice for example it was used in a longitudinal research project into malnutrition in Canadian hospitals to facilitate program implementation and sustainability (Laur and Keller, 2015), and in conjunction with the OMRU to provide the logical underpinning of a rural community knowledge translation project (Campbell, 2010). More recently it was used to guide the increase in the use of knowledge translation in a department in a large hospital in Australia, through which it was found to be a useful tool to begin the process of shaping a knowledge translation culture

(Bennett et al., 2016). Furthermore, Zullig and Bosworth (2015) established that the KTA framework as a useful tool for implementation of knowledge and for helping to create sustainability (Zullig and Bosworth, 2015).

However, whilst the KTA framework has been incorporated into the work of the Canadian Institutes of Health Research, it does still have some limitations. Primarily, and as acknowledged by the authors, further details is need about each phase of the action cycle, as they are not broken down enough to describe what actually needs to be carried out (Graham and Tetroe, 2010b). Moreover, further testing is needed of the framework, which will in turn feed refinement (Graham and Tetroe, 2010b). It is also important to note that the latter studies were published after the commencement of this study.

#### **2.4.7 The Stetler Model of Evidence Based Practice**

The Stetler Model, originally designed and developed for use by clinical nurse specialists, and groups such as project teams (Sudsawad, 2007) (Stetler, 2001) was first developed in 1976 (Stetler, 2010). In its original form it was known as the Stetler Marram Model of Research Utilisation, (Stetler and Marram, 1976), the intention of which, was a guide to facilitate the use of evidence in practice (Sudsawad, 2007). Since its original development, it has been through three iterations by Stetler, resulting in its current form; the Stetler Model of Evidence Based Practice (Stetler, 2010) (Stetler et al., 2009b, Stetler et al., 2009a).

As the original model was not grounded in any conceptual framework, this was addressed in 1994 when the model underpinnings became research in knowledge utilisation and greater based on the theories of organisational and planned change (Stelter, 1994).

Development of the model components saw the model grow from a three phase model of; validation of evidence, comparative evaluation of findings and decision making, to a six phase model, (Uitterhoeve and Ambaum, 1999) with a number of underlying assumptions that supported the phases (Stelter, 1994). The objective of stimulating thinking around the use of research to ensure that research is utilised in an appropriate manner, carries across all the phases;

- Preparation
- Validation
- Comparative evaluation
- Decision making

- Translation / application
- Evaluation (Stetler, 1994)

In 2001 the model was further honed to emphasise the process of data synthesis and evidence use. Greater explanation was given of the preparatory phase, more focus given to the application and evaluation processes and refinement of the assumptions underpinning evidence and differences in practice (Stetler, 2001). Improvements were made to all phases and most noticeably the number of phases was reduced from 6 to 5 as two separate phases; comparative evaluation and decision making, were amalgamated (Stetler, 2001).

Following its third iteration it became a two part model in 2009 (Stetler, 2010), the first part of which consists of five phases; preparation, validation, evaluation / decision making, translation/ application, evaluation (Stetler, 2010). These phases are represented in diagrammatic form and are illustrated as being sequential (Stetler, 2010). The second part of the model is a more in-depth explanation of the phases expressed as six assumptions which have a commentary on possible implications, types of use and influences such as those from the user and the context (Stetler, 2010). The six underlying assumptions of the Stetler model are;

1. The types of evidence used,
2. Organizational involvement,
3. The way that utilization is actioned,
4. Influence of internal and external factors,
5. Probabilistic information not absolutes,
6. Lack of knowledge and skills regarding evidence based practice (a barrier to implementation) (Stetler, 2010).

It is worthwhile noting that assumption 4, *influence of internal and external factors*, acknowledges the impact of context, both local and wider and the beliefs and attitudes of the individual (Stetler, 2010). In its current iteration, it is an interactive model yet remains a prescriptive model, which can be regarded as a critical thinking step by step guide to knowledge implementation from determining the evidence to its implementation and use (Stetler, 2010). However, the model is acknowledged as being extremely complex and too complicated to use at an organisational level (Stetler, 2010). Usage of the model is very dependent on the skills of the facilitator, or those supporting them (Stetler, 2010). The

model has been used mainly by nurses and in particular advance practice nurses (Stetler, 2010). It was used in the Netherlands in the development of an education framework and formulation of clinical standards (Uitterhoeve and Ambaum, 1999) and as a guide to find appropriate research needed to address a research question.

Limitations of this model are in keeping with the limitations that have been identified in the OMRU and KTA. Firstly, despite the fact that the Stetler model is widely used, the authors have identified that it needs to undergo more rigorous testing (Stetler, 2010). Secondly, there is confusion over which version should be used as in the literature they are used interchangeably.

#### **2.4.8 Promoting Action on Research Implementation in Health Services (PARIHS) framework**

The Promoting Action on Research Implementation in Health Services (PARIHS) framework was developed in 1998 by Kitson (Kitson et al., 1998b) (Kitson et al., 1998a) and has been continuously reviewed and improved since (Harvey and Kitson, 2016). It was developed in response to a rise in the use of evidence based medicine and a drive for quality improvement, as a tool to assist the implementation of evidence based healthcare (Rycroft-Malone et al., 2004a). It was developed with clinicians in mind (Kitson Alison. L et al., 2008) and was an acknowledgement that implementing evidence based information such as clinical guidelines and dealing with the barriers that one may face in changing practice, is complex and multifaceted (Bergström et al., 2015).

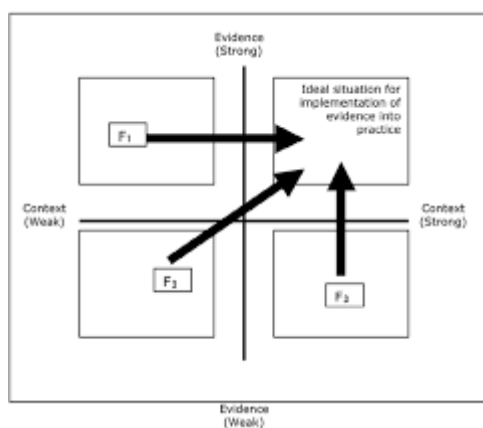
The awareness that there were various factors involved in implementation was in contrast to general thinking at the time (Kitson et al., 1998b), with a particular focus on the importance of context (Estabrooks et al., 2006). Other frameworks as discussed, were available but were represented or worked in a linear fashion, making them difficult to apply (Estabrooks et al., 2006, Kitson et al., 1998b) as not all occurrences happen sequentially. Conversely the PARIHS framework was developed to represent the dynamic inter-relationships of key factors and to provide guidance for an implementation strategy (Kitson et al., 1998b). As contextualised by Ward (Ward et al., 2009) it can be regarded as a dynamic multidirectional model whereby the components may operate simultaneously or at different times to each other.



The PARIHS framework is a multidimensional conceptual framework that proposes three core interacting elements: evidence, context and facilitation, each of which is broken down into interacting sub-elements that influence the successful implementation of evidence based practices (Helfrich et al., 2010). The notion behind the core elements is that for evidence implementation to be successful, clarity is needed about the type of evidence used, the quality of the context and the type of facilitation needed for sustainable and successful change (Rycroft-Malone et al., 2004a).

The original framework (1998) identified three overarching factors; evidence, context and facilitation which are based on the equation  $SI = f(E, C, F)$  meaning that successful implementation (SI) of evidence is a function (f) of the relationship between the three elements; evidence (E), context (C) and facilitation (F) (Kitson et al., 1998b). These three elements all have sub-elements attributed to them which further explain and identify areas of consideration for successful implementation (Kitson et al., 1998b) (Kitson Alison. L et al., 2008) (Rycroft-Malone et al., 2002). The sub-elements have been refined over time as illustrated in Table 3: changes made to the sub-elements of the PARIHS framework 1998 - 2013.

The framework, may be regarded as three dimensional (Kitson Alison. L et al., 2008), for it proposes that for implementation to be successful, when placed on a continuum of high to low, all three factors need to reach high on the continuum (Rycroft-Malone, 2004). In order for high to be reached, there needs to be clarity over the type of evidence, the quality of the context and the type (Rycroft-Malone, 2004)of facilitation required.



**Figure 1: The PARIHS Diagnostic and Evaluative Grid (Kitson Alison. L et al., 2008)**

To achieve high (and thus successful implementation) evidence needs to be scientifically robust, context needs to be receptive to change and facilitation needs to be skilled

(Rycroft-Malone et al., 2004b). It is key, not only to understand each factor on its own but how the sub elements are combined and how the best results can be achieved.

For the purpose of the original framework, the definition for *evidence* was as defined by Sackett et al (Sackett et al., 1996) as being “*research, clinical experience and patient choice*”. This was later adapted to being research, clinical experience and patient experience in 2002 (Rycroft-Malone et al., 2002) and has been further expanded to include local contextual information (Sandström et al., 2015). Whilst it was recognised that randomised control trials (RCT) are regarded as the gold standard of clinical evidence of effectiveness, findings may still be rejected because of the strength of clinical judgement and patient opinion. However, it must be acknowledged that this can work conversely i.e. clinical experience and patient preference may result in the adoption of unsound clinical practices (Kitson et al., 1998b).

In regards to *context*, the original perception was that context relates to the environments / setting in which the knowledge was to be implemented and was broken down into the sub-elements of culture, leadership and measurement (Kitson et al., 1998b). In 2004 it was noted that an understanding of the role played by contextual factors was still developing but the sub-elements of context changed to become; context, culture, leadership and evaluation (Rycroft-Malone, 2004). Within this, culture is classified in many ways; a learning culture, influential leaders, evaluation through measurement (Rycroft-Malone et al., 2002).

*Facilitation* within the PARIHS framework refers to “a process of enabling the implementation of evidence into practice” (Rycroft-Malone, 2004)(p300). The role of the facilitator has multiple interpretations ranging from a hands on approach to a multifaceted role depending on the environment (Rycroft-Malone et al., 2002). The sub-elements of facilitation were identified as purpose, role, skills and attributes (Rycroft-Malone et al., 2002). The type of facilitation employed is dependent on the purpose of the facilitation and the context, illustrating the interplay of the elements. The strength that good facilitation can have is apparent in the argument that poor context can be overcome by strong facilitation, still allowing for successful implementation (Kitson et al., 1998b) (Sandström et al., 2015).

Kitson (1998) (Kitson et al., 1998b) recognised that there is an overlap between facilitation and leadership, the distinction being that local leader opinion relates to changing attitudes

of others whereas facilitation helps guide change. This can be the same person operating in different roles. Facilitation aims to transcend professional organisational boundaries as the focus is not on the professional group but rather the development of interpersonal or group skills (Kitson et al., 1998b). The authors hypothesised that if the implementation of evidence based practice was to be successful a clear understanding of the nature of the evidence, quality of context and type of facilitation is needed (Kitson et al., 1998b). Organisations need to assess these factors and employ appropriate strategies to adopt an implementation plan accordingly.

The authors themselves noted in the original PARIHS framework that it had not been broad enough within context to account for managerial, organisational or political influences, nor possible incentives or sanctions for changing practice (Kitson et al., 1998b). A further initial weakness was identified as being the assumption that the dimensions are causally related, and that it is not known which factor; evidence, context and facilitation has the stronger influence over successful implementation (Kitson et al., 1998b).

In light of this review, i.e. the identification of a suitable model or framework to be used in the cultural translation and adaptation of an evidence based clinical practice guideline, into clinical practice in Malta, a decision was made by the researcher that a more detailed review of the PARIHS framework would be undertaken as it has elements of most resonance i.e. context and evidence are core elements and are key to the study. Therefore, this review continues by looking at the development of the PARIHS framework in further detail.

#### **2.4.8.1 Concept analysis of the PARIHS framework – a review of elements**

The PARIHS framework was designed as a mechanism to implement evidence into practice, stimulate debate and to explore complex theoretical positions. The original notion of the framework was that prior to implementation, the framework would be used as a means of evaluating evidence and the context in which it was to be implemented and on the basis of these findings, mobilise facilitation (Helfrich et al., 2010). As the PARIHS framework was originally based on experience as opposed to an evidence base, a concept analysis of each of the 3 key elements; evidence, context and facilitation, was carried out in 2002 resulting in further modification of the sub elements of the framework (Rycroft-Malone et al., 2002). The concept analysis illustrated that there was a need for greater understanding of the

relationship between the elements and sub-elements of the framework (Rycroft-Malone et al., 2002).

**Evidence:** It confirmed the importance of not restricting evidence to only being research evidence and accepted that different sources of evidence are valued in different ways depending on the audience, for example the interpretation and value placed on evidence by patients differs from that of clinicians (Rycroft-Malone et al., 2002). An understanding was reached that there is a place for qualitative and quantitative evidence including clinical experience, patient experiences and narratives as they are all valid sources and are reflective of the research questions asked (Rycroft-Malone et al., 2002). Important emphasis is therefore placed on the need to critically appraise and analyse evidence appropriately (Rycroft-Malone et al., 2002). This is in keeping with the view that evidence should not be restricted and should encompass that which comes from research, clinical experience, patient and carers, the local context and environment (Rycroft-Malone et al., 2004b). This level of scrutiny is in contrast with the OMRU whereby the quality of the evidence is accepted with an assumption that it is of good quality. Quality of the evidence used in knowledge implementation is integral to its success and the trust that those responsible for implementation have in it (Sandström et al., 2015), therefore there is a risk associated with making assumptions about the quality of evidence.

**Context;** the authors accepted that there was fluidity in the use of the term context and thus regarded that the most important outcome for the concept analysis in regards to the element of context, was a clear definition of its meaning (McCormack et al., 2002). A definition was derived that allowed for an understanding of the influential part that context has to play “*the specific environment in which implementation, utilization and creation of evidence may take place*” (McCormack et al., 2002)(p101). Relating context in this manner conceptualises it as the physical place in which care is provided, with its own individual boundaries and structures (Rycroft-Malone et al., 2002). Context remained as the umbrella element, but it was also added as a sub-element, an indication of its importance when implementing evidence based medicine. The concept analysis emphasised the importance of **culture** and acknowledged its complex relationship with context and how they work together to shape practice (McCormack et al., 2002). Furthermore, recognition was made of the fact that for change to be enduring, an understanding of the different and contrasting cultures present in an organisational context is needed (Rycroft-Malone et al., 2002).

The attention to the impact of context and the sub element of culture are of specific value to this study whereby the focus is on the possible influences these two factors have on the translation of knowledge cross culturally.

**Measurement;** As a result of the concept analysis the sub element of measurement (which is under context) was changed to evaluation as it was regarded as encompassing a broader spectrum of different types of evaluation that can be used (McCormack et al., 2002) such as individual feedback and clinical evaluation (Rycroft-Malone, 2004), plus it takes into consideration the activities of monitoring and feedback (Rycroft-Malone et al., 2002).

**Facilitation;** as with 'context' the concept analysis resulted in a modification of the element 'facilitation' and the identification of aspects which make a facilitator distinct from any other role. The distinctions were outlined as follows; a facilitator is an appointed role, it can be either internal or external to an organisations, the essence of which is to help and guide people (Rycroft-Malone et al., 2002). Thus the basic premise is that the role of a facilitator is a supportive role which works to help people change their practice through guidance and support (Harvey et al., 2002). Facilitation can be employed for a number of purposes with the role of a facilitator covering a wide range of activities e.g. achievement of particular tasks, or development of team dynamics (Rycroft-Malone et al., 2002). The approach that has been taken towards facilitation is that it is multifaceted, allowing for flexibility to suit different types of facilitation to the needs of individual organisations and circumstances. Essentially, the role of the facilitator is to engage on an individual and team level however their success is dependent on a number of variables that include, place of work, the acceptance and willingness to change of others, culture and individual leadership style (Kitson Alison. L et al., 2008).

#### **2.4.8.2 PARIHS becomes a two stage process**

Following these modifications, and a review of work that had been carried out during a ten year period of development and refinement, Kitson et al (Kitson Alison. L et al., 2008) proposed the PARIHS framework as a two stage process of evidence and context followed by facilitation: Stage 1 (evidence and context) produces data outputs which inform the intervention to be applied at stage 2 (facilitation) (Kitson Alison. L et al., 2008). Applying the framework in this way allows for the nature of the intervention to be determined by those operating within the specific context (Kitson Alison. L et al., 2008). The review in 2008 also identified the need for further focus on the theoretical underpinnings of the

framework, greater testing and development of instruments and evaluation methodologies relating to PARIHS and a facilitator training programme (Harvey and Kitson, 2016).

A further addition to the framework was made in 2013 following the use of the PARIHS framework in a process evaluation of a randomised control trial in an acute care setting (Rycroft-Malone et al., 2013). The evaluation led the authors to reconsider the framework, in particular the role of the individual as it was evident the individual did not feature strongly enough within the framework, even though they are key to the process of successful implementation (Rycroft-Malone et al., 2013). The individual was therefore added as another component.

In addition, although it has previously been noted that the PARIHS framework is without distinct theoretical underpinnings (Kitson Alison. L et al., 2008), the authors decided to retain this approach, yet identified a number of theories that link to different components of the framework keeping it flexible and not constrained to a single theory. Table 3 illustrates the development of the PARIHS framework from 1998 – 2013, with changes / additions in bold.

**Table 3: Changes made to the sub-elements of the PARIHS framework 1998 - 2013.**

Year	Paper	Author	Evidence	Context	Facilitation
			Sub-elements		
1998	Enabling the implementation of evidence based practice: a conceptual framework	Kitson et al (Kitson et al., 1998b)	<ul style="list-style-type: none"> <li>• Research</li> <li>• Clinical experience</li> <li>• Patient preferences</li> </ul>	<ul style="list-style-type: none"> <li>• Culture</li> <li>• Leadership</li> <li>• Measurement</li> </ul>	<ul style="list-style-type: none"> <li>• Characteristics</li> <li>• Role</li> <li>• Style</li> </ul>
2002	Ingredients for change: revisiting a conceptual framework  (Following concept analysis, three other papers were produced: Getting Evidence into practice; the meaning of context Getting evidence into practice, the role and	Rycroft-Malone et al (Rycroft-Malone et al., 2002)	<ul style="list-style-type: none"> <li>• Research</li> <li>• Clinical experience</li> <li>• Patient <b>experience</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Context</b></li> <li>• Culture</li> <li>• Leadership</li> <li>• <b>Evaluation</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Purpose</b></li> <li>• Role</li> <li>• <b>Skills and attributes</b></li> </ul>

	function of facilitation What counts as evidence based practice.				
2004	An exploration of the factors that influence the implementation of evidence into practice	Rycroft Malone et al (2004) (Rycroft -Malone et al., 2004a)	<ul style="list-style-type: none"> <li>• Research</li> <li>• Clinical experience</li> <li>• Patient experience</li> <li>• <b>Information from the local context</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Receptive context</b></li> <li>• Culture</li> <li>• Leadership</li> <li>• Evaluation</li> </ul>	<ul style="list-style-type: none"> <li>• Purpose</li> <li>• Role</li> <li>• Skills and attributes</li> </ul>
2008	Evaluating the successful implementation of evidence into practice using the PARIHS framework: theoretical and practical challenges	Kitson et al (2008) (Kitson et al., 2008)	<ul style="list-style-type: none"> <li>• <b>PARIHS is a two stage process:</b> <ul style="list-style-type: none"> <li>○ <b>stage 1 - evidence and context</b></li> </ul> </li> </ul> <p><b>The outputs of evidence and context inform the intervention (facilitation process).</b></p>		<ul style="list-style-type: none"> <li>• <b>Stage 2 – facilitation process</b></li> </ul>
2013	The role of evidence, context, and facilitation in an implementation trial: implications for the development of the PARIHS framework.	(Rycroft -Malone et al., 2013)	<ul style="list-style-type: none"> <li>• Addition of a fourth element; individuals</li> </ul>		

#### 2.4.8.3 The i-PARIHS framework 2016

In 2016, a revised framework, the integrated-PARIHS or i-PARIHS framework (Harvey and Kitson, 2016), was published following a further review of the three key components; evidence, context and facilitation which resulted in renaming evidence as innovation, the addition of a new component; recipient and the central positioning of facilitation. Changes to the framework were explained as follows:

- Innovation encompasses the variant ways in which evidence is produced and accepts that knowledge is often adapted prior to implementation.

- Addition of recipient acknowledges those that are responsible for the implementation of knowledge and recognises the impact that they have as they are a product of their views, values, beliefs and practice. It encompasses patients, clients, managers and clinical staff and is an umbrella over those that affect implementation and those affected by implementation.
- Context is still regarded as a core construct but focus is more on the multi layers of context accepting that context relates to both the local context (the immediate setting) and the wider context (health and political system).
- Facilitation has been identified as being central to implementation and is the trigger for the whole process. The facilitator role is integral, whether it is an internal or external role, and thus to support this, a facilitators tool kit was produced (Harvey and Kitson, 2016).

The developments mentioned are illustrated in the representation of the new framework whereby successful implementation is achieved through the facilitation of innovation, recipient and context, making facilitation key to the process.  $SI = Fac^n (I + R + C)$  (Harvey and Kitson, 2016). The authors claim this is a new framework it will need further development and refinements and future testing to establish validity.

#### **2.4.8.4 Use of the PARIHS framework**

In keeping with the other frameworks discussed, utilisation of the framework is continuously growing, as such it has been used to inform other frameworks (Damschroder et al., 2009) (Majdzadeh et al., 2008) (Doran and Sidani, 2007) (Ullrich et al., 2014), used as a framework for implementing knowledge in various contexts such as in a neonatal unit in Vietnam (Wallin et al., 2011) and in residential aged care in Australia (Perry et al., 2011). It has also been translated into Swedish for utilisation by nurses in Sweden (Sandström et al., 2015) and also used in Sweden to support the uptake of evidence in practice (Wallin and Ehrenberg, 2004). In a review of its use by the US Department of Veterans Affairs (VA) Quality Enhancement Research Initiative (QUERI) program, it was identified that the PARIHS framework had been used in a variety of ways either as guidance for the overall implementation of a project or to guide a specific project aspect both prospectively and retrospectively (Ullrich et al., 2014)). Rycroft-Malone et al (2012) used the PARIHS framework to underpin a pragmatic cluster randomised trial looking at the effectiveness of strategies for implementation of clinical practice recommendations about peri-operative fasting (Rycroft-Malone et al., 2012 -b). Reasons for using the framework include its



flexibility allowing it to be used in different settings and its ability to identify the intrinsic elements of implementation (Helfrich et al., 2010). More recently Choowong et al (Choowong et al., 2016) used the PARIHS framework as a retrospective tool to gain an insight into management practice of applying tuberculosis guidelines in Thailand.

Acknowledgement of the three elements having equal importance has been made but (Sudsawad, 2007), it is unclear as to whether this is actually the case. Kavanagh et al (Kavanagh et al., 2007) explored this further when examining factors enabling successful implementation and focussing on context and facilitation, supporting the idea that these two elements are of great importance to the implementation of knowledge. The importance and relative weighting of each element is recognised by the authors as something that needs to be further explored (Rycroft-Malone and Bucknall, 2010). Other researchers have chosen to focus on one element of the framework such as Bergstrom (Bergstrom et al., 2012) who wished, to identify whether there were other factors relevant to a low income country, that would need to be included under the element of context. Although there is a question as to whether one element is more important than another or whether they have equal importance makes a worthwhile consideration, it does lead one to question whether such assessment is necessary. That is to say, each situation is different and therefore may need greater focus on for example facilitation as opposed to context.

The comprehensiveness of the PARIHS framework has resulted in its functionality being challenged (Sudsawad, 2007), bringing into question whether or how it can be delivered at an individual level (Rycroft-Malone and Bucknall, 2010). On the other hand, the framework has both been praised for its simplicity and clarity and criticised for it at the same time (Ullrich et al., 2014). As is the case with all theories, frameworks and models, such questions can only be answered through further testing.

Limitations of this model have been identified as:

- Further testing of the framework is needed (Estabrooks et al., 2006) (Kitson Alison. L et al., 2008).
- More work need to be undertaken to understand the interactions between the elements and sub-elements to ensure that appropriate interventions are designed for the translation of evidence into practice (Kitson Alison. L et al., 2008) (Helfrich et al., 2010).

- Understanding on whether each element has equal importance (Sudsawad, 2007)
- Clearer definition of what is meant by successful implementation (SI) (Helfrich et al., 2011)
- Lack of validated measurement tools (Ullrich et al., 2014).

## **2.5 Further framework elements to be considered.**

### **2.5.1 The patient**

A further area to be discussed which was identified as being insufficiently addressed in any of the frameworks reviewed, is the role of the patient. In the PARIHS framework, patient experience is included in regards to evidence but not addressed in a comprehensive manner for facilitation or context (although this is addressed in the new i-PARIHS framework (Harvey and Kitson, 2016)). Patient involvement lends itself to being a theme that runs through these frameworks, allowing for patients to be considered at all stages. In the OMRU patients are included under the heading 'practice environment' and in 'outcomes' but not in a dynamic sense, it seems they are included because they are there and not because they are to be engaged with in the process of knowledge implementation. There is no overt mention of patient involvement in either the KTA or the Stetler Model of Evidence Based Practice. As the essence of these models is to improve patient care and ensure that healthcare practices are current, it can be surmised that their inclusion in these models requires further attention.

### **2.5.2 Culture within knowledge implementation frameworks.**

As culture has such an impact on the way in which the world functions, it is worthwhile to identify whether culture is considered in the four main frameworks reviewed and if so, how. (Section 2.7 looks at culture in more detail).

**Table 4: Consideration of culture in the four main frameworks reviewed.**

<b>Model / framework</b>	<b>Culture as an element</b>	<b>Culture as a sub-element</b>	<b>Definition of culture</b>	<b>Other inclusion</b>
The Ottawa Model of Research Use (OMRU)	No	Culture is a sub-element of 'practice environment'. Practice environment is regarded as 'structural factors' (Logan and Graham, 2010)	A joint definition of culture / social <i>"belief systems within the setting, local politics, personalities and leadership, peer influences, endorsement of the change by local champions"</i> . (Logan and Graham, 2010) page 87.	
The Knowledge to Action (KTA) framework	No	No	No	The action phase occurs in a context which takes into account context / culture. This is determined as the "physical, social and organisational aspects of the implementation environment" (Graham and Tetroe, 2010a) p 214). The authors of the framework note the importance of understanding local context as a means of making change more successful.

				(Graham and Tetroe, 2010a)
Stetler Model of Evidence Based Practice	No	No	No	
Promoting Action on Research Implementation in Health Services (PARIHS) framework	No	Culture is a sub element of 'context', alongside receptive context, leadership and evaluation. Context is regarded as "the environment or setting that the proposed change is to be implemented" (Rycroft-Malone, 2010a)(p123)	Culture is depicted in terms of prevailing values and beliefs of the organisation. The characteristics of culture all relate to the organisation e.g. valuing people who innovate, promotion of learning, the value of open communication. (Rycroft-Malone, 2010a)	

Culture is not identified as a primary element in any of the four models/ frameworks, yet the OMRU and the PARIHS framework both include culture as a definitive sub-element. The PARIHS framework identifies it on its own, whereas the OMRU amalgamates it with a sub-element 'social'. By not defining it as a separate entity to social, it makes it unclear as to which part of the explanation refers to culture and which to social, thus perhaps muddling the two concepts of culture and context. The definition does however include the individual and thus one could surmise that culture has an influence here. From the definition provided in the PARIHS framework, it is apparent that culture is regarded as an independent entity. It does however appear that the focus is on organisational culture, as the organisation is the hub around which the definition of culture flows. Whether this definition will extend to include the culture of the individual, since the addition of the 'individual' to the framework in 2013 is yet to be seen.

How culture will be defined for the purpose of this study will be discussed in the subsequent section entitled Culture: the breadth and complexity.

## **2.6 Framework selection**

Following the evaluation of these four frameworks, taking into consideration their key elements and functionality, the PARIHS framework was identified as being the most suitable for this study. The decision to use the PARIHS framework is predominately due to the following points that are central to this study;

1. Emphasis on high quality evidence – this is of particular importance within this study as a clinical guideline will be developed in order to test the elements of the PARIHS framework for cross cultural utility. As an integral part of the guideline development is the quality of the evidence and an assessment of this, the inclusion of evidence as a key component is pivotal as it is central to guideline development.
2. The prominence of context and culture within the framework – this is fundamental to this study as cultural translation of knowledge is a key element and therefore it is important that context and culture are acknowledged within the framework to be used. Therefore, whether culture and context are strong enough elements in the PARIHS framework will be ascertained.
3. An environment that is receptive to change and is promoted and supported by the presence of skilled facilitation (Rycroft-Malone et al., 2004 ). As the study focuses on the development of a clinical guideline, the receptiveness of the environment, in particular healthcare professionals, management and patients' receptiveness to change is of importance in regards to the implementation of the guideline.

Thus as acknowledged by Ullrich et al (Ullrich et al., 2014) the three elements of context, facilitation and evidence are a reflection of the factors integral to knowledge implementation and are therefore essential to this study.

In addition, the development of the PARIHS framework into a two stage process; stage 1 (evidence and context) produces data outputs which inform the intervention to be applied at stage 2 (facilitation) (Kitson Alison. L et al., 2008), suits the design of the study as the evidence will be presented within the context of Malta and discussion will be facilitated to create recommendations to be implemented.

With this in mind, it is important to note that this work uses the 2008 (Kitson Alison. L et al., 2008) version of the PARIHS framework. The reasons for this are two fold; it was the most established version when work on this study commenced, it has been more thoroughly tested and is shown to have both face and concept validity and conceptual integrity (Kitson Alison. L et al., 2008). The two versions that were developed following this, Rycroft Malone 2013 (Rycroft-Malone et al., 2013) and Harvey and Kitson 2016 (Harvey and Kitson, 2016), were developed post the commencement of this study. The i-PARIHS is a new iteration, recently published, by a sub-group of the original authors and for which these authors are currently requesting feedback (Harvey and Kitson, 2016).

The PARIHS framework (2008) will be used to guide the development of an evidence based clinical practice guideline and will be evaluated to ascertain whether it has cross cultural utility. The following points are a brief summary as to why the other three model/frameworks were not chosen.

1. The OMRU is a practical model, targeted to a multidisciplinary audience, with an acknowledgement of culture under the key element of 'practice environment' i.e. context. However, the quality of evidence is assumed rather than being assessed. This latter component makes it less suitable when the quality of evidence is integral to the study.
2. The KTA can be used by a wide audience including the public, stakeholders, and multidisciplinary healthcare professionals. There is a strong emphasis on adaptation of information to the context, yet the quality of evidence is questionable. Again it is the lack of integrity regarding evidence quality that makes this framework less suitable.
3. The Stetler model was designed for clinical nurse specialists and project teams. It includes a component referring to the 'context' and uses critical appraisal in the assessment of knowledge, yet overall it is prescriptive and complicated to use, not making it flexible enough for this study.

### **2.6.1 The contribution of this study**

This study proposes to contribute to the literature on the use of the PARIHS framework in two areas. Firstly, it wishes to test the framework's applicability for use in the adaptation of an evidence based clinical practice guideline. That is to say, it aims to see if the elements of the framework can inform the development of the guideline and extend to identifying the challenges and barriers of this process. Secondly, although the PARIHS framework has

been used internationally, this study wishes to explore its appropriateness for cultural translation and adaptation, thus testing the strength of the components of context and culture. Furthermore the opportunity will be taken to explore the interactions between the elements and the sub-elements and understanding whether each elements carries the same importance.

Following the review the research questions to be addressed are;

1. To explore the appropriateness and utility of the PARIHS framework, in the cultural translation and adaptation of an evidence based clinical practice guideline into clinical practice in the healthcare system in Malta<sup>2</sup>.
2. To identify the challenges and barriers to successful cultural translation and implementation to inform future cross cultural knowledge translation programmes.

Central to this study is culture and the effect it has on the translation of knowledge into practice. Therefore the subsequent section is an exploration of culture, its breadth and complexity and relevance to the healthcare environment. As an outcome of this discussion, a definition of culture to be used in this study will be provided.

## **2.7 Culture: the breadth and complexity**

### **2.7.1 Introduction**

Defining culture is a real challenge. There are a range of definitions with there being no absolute definition of culture as it is a word, a concept that is used in a plethora of ways to mean many different things. However, it is important for the purpose of this study to present an understanding of what culture is as an overriding concept and within a healthcare organisation and how it is understood in the study. Consequently this section aims to provide an overview of the origins of the word culture, the complexity involved in defining it and a brief insight into the discussions surrounding this. Organisational culture and context within healthcare will then be explored.

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<sup>2</sup> This study began with the Royal Jordanian Medical Services, however due to unforeseen circumstances the study site had to be changed to Malta. See Chapter 2 for further explanation and background.

### 2.7.2 Defining culture

Defining culture is fundamentally difficult (Cohen, 2009). As Raymond Williams states in his book, *A Vocabulary of Culture and Society* “*Culture is one of the two or three most complicated words in the English language*” (p25) (Williams, 1976). He continues by saying that this difficulty can be attributed to the fact that the word ‘culture’ has evolved over time and is used in various conceptual ways and by many different disciplines (Williams, 1976). For example, culture is used to describe; the arts as culture is music, literature and theatre; a group of people or a way of life and used for the description of a process of intellectual development (Williams, 1976). The evolution of ‘culture’ as a concept moved it from a noun identifying a practical process, *cultura*, meaning cultivation or tending in Latin, to a word used to describe a process of human development in the sixteenth century (Williams, 1976). This development continued resulting in a definition of culture being written in the late 18<sup>th</sup> century, from an anthropological perspective; “*culture or civilization, taken in its wide ethnographies sense, is that complex whole which includes knowledge, belief, art, morals, law, custom, and any other capabilities and habits acquired by man as a member of society*” (p1) (Tylor, 1920)

Since the definition given by Tylor (1920) (Tylor, 1920) there has been continuous complex debate among a range of disciplines; anthropological, sociological, psychological, business management (Ryan et al., 2014b) all producing varying definitions to incorporate their particular viewpoint. A range of definitions or attributes of culture was highlighted by Kroeber and Kluckhohn (1952) following the collation of 164 definitions of culture which they categorised into groups according to the focus of the definition; content, social heritage or tradition, rules, ways of doing things and psychological definitions (Kroeber and Kluckhohn, 1952). This amalgam of definitions succeeded in illustrating the expansive influences of culture, yet attracted criticism of it being too inclusive and verbose, making it difficult to identify the core components that make up culture (Keesing, 1974).

There are however what may be regarded as key definitions, in particular that written by Clifford Geertz, an anthropologist, credited with writing seminal texts on the definition and understanding of culture. On a basic level, Geertz noted that no one is immune from the influence of culture, as people live according to the rules and structures that it provides (Geertz, 1993). That is to say; “*culture is composed of psychological structures by means of which individuals or groups of individuals guide their behaviour*” (Geertz, 1993) (page 11). This definition builds on the work of Goodenough (1957) who developed the idea of



structures and rules to encompass knowledge and beliefs, by stating that a *“society’s culture consists of whatever it is one has to know or believe in order to operate in a manner acceptable to its members”* (Goodenough, 1957) (p167). However, whilst this may explain the basic function of culture, it does not identify the various components that collectively form ‘culture’ or those that make up individual cultures. It is only through such identification that the differences in culture can be seen. Goodenough continues to note that culture is something that is learnt and is an organisational mechanism through which behaviours and emotions are interpreted (Goodenough, 1957). Geertz (Geertz, 1993) addresses this by stating that culture is not made up of a set of behavioural patterns, but instead is a set of what are regarded as ‘control mechanisms’ or perhaps confines that one has to operate within such as rules, regulations or instructions and the role of which is to govern behaviour. According to this definition, one lives life dependent on the parameters of the culture in which they live, and thus it may be considered that we are equipped to live within any cultural framework (Geertz, 1993) and that it is just life that dictates which one. Keesing (1974) a contemporary of Geertz illustrates his agreement through the identification of two main systems of culture, a) culture as an adaptive system; a social system of behaviour that adapts and responds to societal changes and challenges, b) culture as an ideational system; based on cognition (including language), knowledge, symbols or meanings (Keesing, 1974). In keeping with Geert’s view, Keesing (1974) concluded the latter, as being the meaning that would lead to better understanding and insight into the complexity of culture.

Geertz’s work however relies on the importance of values and their effects on action. Yet this has been criticised as being an insufficient definition, if one wishes to truly understand the affects culture has on action (Swidler, 1986). In Geertz’s schema of culture, values are the central causal component of culture influencing actions (Geertz, 1993). However, Swidler (Swidler, 1986) proposes that values, whilst being sufficient for the explanation of culture, are not enough for the interpretation of culture. She outlined three steps to understanding culture; firstly, that values should be replaced by an extensive system whereby culture is regarded as a collection of tools comprising of, for example, customs and skills to be utilised for problem solving, secondly the influences that culture has on identifying the most appropriate way to act within a situation once all cultural cues have been read, thirdly, by analysing these different factors, it is proposed that this will result in a deeper understanding of the causal role of culture (Swidler, 1986). According to

Swidler (1986) culture is a culmination of factors such as customs and behaviour which informs an individual's plan of action (Swidler, 1986). According to Cohen (Cohen, 2009), the difference between the definitions provided by Swidler and Geertz can be summarised as; a) the former refers to the information in culture and b) the latter focuses on the meaning of culture a subtle but distinct difference. Culture is therefore made up of a number of different components, used individually or in conjunction with each other to construct both meaning and action (Swidler, 1986).

### **2.7.3 Everyday culture**

It has been established that culture is not a fixed uni-dimensional concept, operating within a vacuum. Everyone is affected by some form of culture, as people exist in sociocultural environments created of shared values, customs and social practices, which create 'diverse and dynamic social systems' (Bandura, 2002) (p269) and which are affected by the actions of individuals. Regarding culture in such a dynamic form is supported by Zoreda (Zoreda, 1997) who identifies culture as *"a fluid phenomenon that is difficult to enclose within neat boundaries"* (Zoreda, 1997)(page 3). These definitions which view culture as a dynamic state provide further insight not just into the complexity of 'culture' but illustrate it is not something that is static and that can be compartmentalised or easily packaged, as it is affected by both individual and collective views (Ryan et al., 2014b). Furthermore, what is important is that one should remember that culture is ever changing and developing over time (Davies et al., 2000b) (Zoreda, 1997).

The view that culture is adaptable and changeable is expanded by Bandura (Bandura, 2002). He uses social cognitive theory, a means of explaining the way in which people act, to examine the use of different modes of agency and the variation of these cross-culturally, to provide insight and explanation into how the individual affects culture and culture affects the individual (Bandura, 2002). Agency as referred to here is the ability of an individual to influence things or make things happen by their own actions (Bandura, 2001). The concept of being able to influence events is particularly important when considering the implementation of knowledge and the role that individuals, teams and organisations have. It is also in keeping with both facilitation and the individual being key elements in the PARIHS framework (Rycroft-Malone et al., 2013), indicating the importance of their role and why an understanding of the cultural nuances of the situation is essential. Social Cognitive Theory identifies three types of agency (individual ability to influence);

1. Direct personal agency (individual action)

2. Proxy agency (someone acting on behalf of another)
3. Collective agency (the actions of a group)

These three agencies are relevant cross culturally, yet it is the diversity of culture that influences them (Bandura, 2002). The agencies alone however are not enough for people to function in society, there needs to be a mix of agencies as outlined above plus an element of self-efficacy (Bandura, 2002). He continues to acknowledge that this mix and the levels of self-efficacy vary cross-culturally as some cultures have a more individualised orientation (individualistic) whilst others are more collective (collectivist) (Bandura, 2002). Bandura (Bandura, 2002) emphasises that it is the downplay of such cultural subtleties when comparing cultures that results in the generalisation of cross-cultural similarities and or differences. Heterogeneity is also identified as being present within individualistic and collectivistic societies (Bandura, 2002) further suggesting that culture cannot be a label that is applied without an acknowledgement that culture is multifaceted and complex.

The idea that culture is multidimensional and complex, is addressed by Cohen (2009) who notes that people can share cultures whilst at the same time be culturally different (Cohen, 2009). Cohen focuses on three kinds of culture; religion, socioeconomic status and region in a country, so that a clear picture can be formed of how one person can experience or be a part of more than one culture (Cohen, 2009). This is particularly pertinent to this study where consideration of the micro, meso, macro culture needs to be made. Looking further at the multidimensional nature of culture Bandura (Bandura, 2002) notes how globalisation and technology, such as the internet has resulted in cultures no longer existing in isolation and also the demise of cultural uniqueness (Bandura, 2002). Whether this suggested demise should be regarded negatively is debatable as, culture, whichever aspect is being focused on or definition adhered to, is dynamic and thus the influences of technology and what may be regarded as the modern world and the changes this brings are the ever evolving nature of culture (Zoreda, 1997). However, it has been stated that one should not lose sight of the importance of the individual country, for although there are global influences, country context remains influential (Wrede, 2010).

#### **2.7.4 Cross cultural communication**

Culture is clearly made up of many different components, with which there are various influential relationships. One such relationship is the link between culture and language. Language has been identified as being a part of culture (Keesing, 1974), with it having been

said that *“language and culture are intermeshed as social practice”* (Zoreda, 1997) (p293), illustrating their symbiotic relationship. Whilst language has been recognised as an extension of culture, its practical influences have also been noted. In particular, cultural barriers can be caused by language reducing accessibility to all, for example, if people speak different languages or different dialects of the same language, if workplace culture results in the use of specific jargon or if abbreviations or professional language are spoken (Bednarz et al., 2010). The language barriers identified here are applicable to the research proposed as such influences may impact on successful cultural translation and adaptation if not heeded to. An aspect of the research is to help to establish how the PARIHS framework works within a cross cultural context and the barriers that may be associated with this. In doing so, it will also help to understand whether the definition of culture within the PARIHS framework or the focus that the framework gives to culture is appropriate or needs further consideration. In particular in regards to language, the language used for recommendations within NICE guidelines is very specific and is reflective of the strength of the evidence. In turn this influences the types of words used (National Institute for Health and Care Excellence, 2017). However, it will be interesting to see whether this use of language translates culturally or whether when writing the recommendations for this guideline, a different form of words is preferred.

#### **2.7.5 Organisational culture**

As noted, culture is multidimensional and influences or is influenced by a number of factors. One specific area of culture that is relevant in healthcare, is organisational culture. The rise in interest in organisational culture started in the 1980's, since when interest has continued to grow (Davies et al., 2000b). Much like trying to define culture, a definition of organisational culture is equally as challenging and as a result varying definitions have emerged over the years (Davies et al., 2000b) (Scott-Findlay and Estabrooks, 2006). A definition by Scott-Findlay (Scott-Findlay and Estabrooks, 2006) is based upon Bower (1966) identification that a work place will grow and develop to a point that the way things happen become a norm within the environment that they are occurring in (Bower, 1966). This resulted in Scott-Findlay (Scott-Findlay and Estabrooks, 2006)(p499) defining organisational culture as providing *“a sense of what is valued and how things should be done within the organisation.”* To consider this in greater depth, the culture of an organisation impacts on the way an organisation functions, and can be defined as being concerned with the processes involved in creating meaning and action (Pearse, 2009),

which is in keeping with the definitions of culture as stated previously by Bandura (Bandura, 2002) and Swidler (Swidler, 1986). The recognition stated here of the impact that the culture of an organisation can have on its function is of particular resonance as the definition of culture within the PARIHS framework sees culture as being depicted in terms of the organisations beliefs and values.

Aside from focusing on the direction that an organisation moves in culturally and the influences of direct action, there is also a perspective that culture pertains to the essence of an organisation. That is to say, that in the same way as society being a culture, an organisation is a culture in itself as opposed to being regarded as having a particular culture (Bate, 1994). Davies et al (Davies et al., 2000b) develops this concept further and refers to *is* and *has* as two entities to be addressed separately. According to Davies, if culture is something the organisation *is* then it is possible to create change and manage the culture yet if culture is something the organisation *has* then creating change is a greater challenge (Davies et al., 2000b). This has resonance in the arena of knowledge implementation, when one considers that knowledge implementation is reliant on many factors of an organisation; facilitation, receptiveness to change, culture and context for the uptake of knowledge implementation to be successful. The latter explanation of culture would therefore make the implementation of knowledge difficult and a process whereby more barriers may be encountered. Consideration of how culture operates within an organisation and the impact that this can have on implementation is clearly important. The use of a framework such as the PARIHS framework may assist in facilitating this and overcoming such barriers. The effectiveness of the PARIHS framework in this manner will be assessed in this study.

Whilst this is a broader view it does not address the dynamic nature of culture and how it changes over time. As with everyday culture, organisational culture is continuously developing and in doing so, consideration needs to be given not only to the present but the past too, emphasising the importance of historical context (Pearse, 2009). In a review of organisational culture Scott-Findlay et al (2006) identified the themes of shared values, norms and assumptions as key features of organisational culture (Scott-Findlay and Estabrooks, 2006). This is supported by Davies et al (2000) who extends these determinates of organisational culture to include shared beliefs and behavioural norms which are evident in any organisation (Davies et al., 2000a)(Davies et al., 2000b)(Scott-Findlay and Estabrooks, 2006).

This latter point moves from the focus which has largely been on the place or situation in which culture occurs. It is however important to note that organisational culture, like 'culture' is about shared characteristics of people in particular pertaining to their shared beliefs, traditions, behavioural norms and values (Parmeli et al., 2011), (Davies et al., 2000b). This is supported by a review of organisational culture carried out by Scott-Findlay (Scott-Findlay and Estabrooks, 2006) whereby the themes of shared values, norms and assumptions were identified as essential features of organisational culture. Additionally, it is key to recognise that organisations are affected by external cultural influences, such as national context, political, economic and social factors, as an organisational culture does not exist in isolation (Davies et al., 2000b) (van Oudenhoven and Zee, 2002).

Organisational culture is obviously situated in a national culture, therefore for international cooperation to be successful when working cross culturally, it is vital that an understanding of the culture of the partner country is achieved (van Oudenhoven and Zee, 2002). The importance of such understanding cannot be underestimated. Weissenberger-Eibl and Spieth (Weissenberger-Eibl and Spieth, 2006), from a business perspective proposed that national and organisational culture have a mutual relationship with the former driving the latter. They point out that when working cross culturally, one needs to be aware that national and organisational cultures may be "*convergent, compatible or different*" (Weissenberger-Eibl and Spieth, 2006)(p71) with differences arising mostly in regards to, "*perceptions, values and actions*" (Weissenberger-Eibl and Spieth, 2006) (p71). The identification of these 3 constructs is in keeping with previously identified cultural themes.

#### **2.7.6 Knowledge transfer and culture**

Thus within this study, concerted effort will be made to understand the culture, be aware of cultural difference and respectful to them. When considering the above in relation to knowledge transfer (Weissenberger-Eibl and Spieth, 2006) identified the multifaceted influence of culture by indicating that the role organisations have, which are influenced by their cultures, is only one factor in successful knowledge transfer as there are other influences including individual cultural background and whether an organisation is supportive or opposes to knowledge transfer. On the other hand some regard the influence of culture as being so strong, that knowledge cannot be divorced from the culture in which it originates, or to take it further it cannot be understood outside of its cultural parameters (Weir and Hutchings, 2005). This latter view is particularly restrictive when one

considers the importance of international knowledge transfer whether it is in healthcare, trade or commerce.

However, the debate resonates with this study, whereby cultural influence on knowledge translation is to be assessed through the evaluation of the cross cultural utility of the PARIHS framework. Through this process the barriers to cross cultural implementation of knowledge can be further identified. In turn it is hoped that by addressing these barriers, healthcare guidelines can be successfully implemented through appropriate cultural adaptation. Thus far it has been established that an organisation is a culture in itself (Bate, 1994), which is a notion that relates to all organisations. To look at how this applies to healthcare, the following section provides an exploration of healthcare culture and context.

### **2.7.7 Healthcare organisational culture**

As established, the definition of organisational culture pertains to the place in which a culture exists (Davies et al., 2000b) (Bate, 1994), the people within that setting and the influences they exert (Parmeli et al., 2011), with the adage of external influences (Davies et al., 2000b) (van Oudenhoven and Zee, 2002). Healthcare organisational culture is therefore just one example of an organisational culture. As organisational culture has been discussed, this section will explore organisational culture specifically relating to healthcare. The healthcare environment is a complex organisation with numerous influences which effect the care that is delivered and ultimately patient outcomes (Scott-Findlay and Estabrooks, 2006). In regards to healthcare delivery, culture is perceived as being the overriding factor in areas such as clinical effectiveness and successful outcomes (McCormack et al., 2002). This can become complicated when one considers that within the same environment different cultures can exist, that is to say for whilst culture is something that can be shared, it is also something that is entrenched in the individual, and it is these individual cultural nuances which can affect practice (Pearse, 2009). Davies et al (Davies et al., 2000b) strengthens this notion and expands it by identifying three levels of culture within healthcare, which all affect the delivery of healthcare care in one way or another. They are;

- a) the unconscious level: beliefs that are taken for granted,
- b) the conscious level: standards and goals and
- c) the concrete manifestations of culture: traditions and insensitive structures

(Davies et al., 2000a)(Davies et al., 2000b).

He states that these are not necessarily the same within one organisation and that it should be recognised that different cultures can emerge within different occupational groups and departments (Davies et al., 2000b). The importance of this acknowledgement, particularly comes into play when existing cultures conflict as this can lead to dysfunctional ways of working and undesirable working relationships (McCormack et al., 2002). For example Nzinga et al (2009), in a study looking at barriers to guideline implementation in Kenyan hospitals noted that the existence of a hierarchical culture prevented involvement from healthcare professionals who were regarded as being at the lower end of the hierarchy (Nzinga et al., 2009). The identification of hierarchical culture here, substantiates the importance of being aware of the function and influences of culture and the necessity to be sensitive to them (Davies et al., 2000b), no matter what environment somebody is working in. This is a much more complex and multifaceted view of culture than the PARIHS framework affords it, bringing into question whether the definition of culture in the PARIHS framework needs to be of greater depth.

### **2.7.8 Healthcare organisational context**

As the above example describes, organisational culture exists within a *context*, i.e. within an organisation (Scott-Findlay and Estabrooks, 2006). In healthcare the context is the healthcare environment or more precisely the 'environment or setting in which people receive healthcare services' (McCormack et al., 2002) (p96). Contexts in which healthcare services are provided are complex dynamic environments (Rycroft-Malone et al., 2012 - b)made up of a whole host of settings, cultures and communities and are created out of the individual, organisations and team cultures (McCormack et al., 2002). Within this complexity, the context of the workplace has a dual influence; it contributes to patient outcomes and also influences provider outcomes (Wallin et al., 2011). The importance of including contextual aspects in the implementation of evidence based practice was highlighted by Wallin et al (Wallin et al., 2011), whilst examining the contextual factors that influenced the implementation of evidence based nursing. This confirmed the strength and importance of context as a contributing factor to organisational development and learning. This is extended by Bergstrom et al (Bergstrom et al., 2012) who, in a study of knowledge translation in Uganda, argued that if context is appropriately considered then implementation strategies would be more successful. Although the distinction between culture and context may seem unclear, what these examples show is that the context in



which a service is delivered, or into which knowledge is to be translated, is influential in itself but is also itself influenced by the nature of the various elements of culture.

### **2.7.9 Context and culture**

Consequently one can say there is a relationship between culture and context with the two interacting with each other, however this relationship and how it works is complex and can be opaque (McCormack et al., 2002). This lack of clarity is noted by Wallin et al (Wallin et al., 2011) who argue the difference between the primary organisational factors which contribute to the implementation of evidence based practice primarily; organisational culture, context, work environment are not clear. Consequently this makes it difficult to identify the influence that each holds. Whilst it may be simpler to define a context, it is the understanding of the culture of a setting, that needs to be achieved if sustainable change is to occur within a healthcare environment (McCormack et al., 2002). By referring to the environment as the context, culture can be conceptualised as a characteristic of context (McCormack et al., 2002).

### **2.7.10 Summary of definitions of culture**

The above is an illustration of the complexities surrounding the definitions and function of culture. The following quote from Geertz (Geertz, 1993) (p37) is thus very fitting, as it demonstrates the multifaceted nature of people, with a view to how these 'layer' impact on culture and indicates the challenge of defining culture.

*"As one analyses man, one peels off layer after layer, each such layer being completed and irreducible in itself, revealing another quite different sort of layer underneath. Strip off the motley forms of culture and one finds the structural and functional regularities of social organisation. Peel off these in turn and one finds the underlying psychological factors – "basic needs" or what –have-you- that support and make them possible. Peel off psychological factors and one is left with the biological foundations – anatomical, physiological, neurological – of the whole edifice of human life." (Geertz, 1993)*

One may therefore say it is difficult to attribute culture to one meaning as there is not an over-riding definition that successfully captures all that is culture. Hence a definition of culture is dependent on what it is being applied to, for example whether it is a description of an organisation, culture within a subset of society or a national culture, therefore suggesting that 'culture is a characteristic of context' (McCormack et al., 2002). The

concept that organisational culture can be perceived as two separate entities of *is* (something an organisation is) and *has* (something an organisation has) and that the latter makes change more challenging (Davies et al., 2000b), is a useful guide to how to acknowledge culture within an organisation. Then there is the impact of culture on the individual and the individual on culture. In its simplest form, the way in which people live their lives is formed by their culture (Swidler, 1986) as culture is regarded as a set of 'control mechanisms' (Geertz, 1993) through which one leads their life and thus enables someone to live life anywhere, as they understand how to process the host culture.

### **2.7.11 How culture is to be used in this study**

To decide which definition of culture has most resonance within this study is a difficult task, for the reasons outlined above. The purpose of the study is to examine whether the components of the PARIHS framework are applicable in a culture which significantly differs from the cultural environments in which the framework was developed and primarily tested. If change is to occur then the culture of the healthcare context in which it is to take place needs to be understood (McCormack et al., 2002). In doing so, the wider culture also needs to be understood and therefore within this study identification regarding a definition is with a number of concepts as opposed to one definition. This study is supportive of the view that culture is a dynamic state that is affected by both the views of the individual and the collective (Ryan et al., 2014b). Culture itself is a culmination of factors such as values, skills and customs through which one creates understanding and action (Swidler, 1986). As these attributes are varied and can be applied to different types of culture such as religion, socioeconomic status and country region, one can be part of more than one culture (Cohen, 2009). An adage to this is the importance of language as this too is intertwined with the other aspects mentioned (Zoreda, 1997). Finally, when referring to organisational culture it should be seen as being formed from shared characteristics of people; their shared beliefs, traditions, assumptions, behavioural norms and values (Parmeli et al., 2011), (Davies et al., 2000b) (Scott-Findlay and Estabrooks, 2006). Considering the study focuses on the use of the PARIHS framework cross-culturally, acknowledgement needs to be given to the fact that organisations do not exist in isolation and are affected by external cultural influences, such as national context, political, economic and social factors, (Davies et al., 2000b) (van Oudenhoven and Zee, 2002). The definition that the PARIHS framework uses to describe culture will also be considered. Finally, it would also be appropriate to consider how the use of the PARIHS framework can

contribute to culture for perhaps by using it to facilitate knowledge implementation, it can help to create a culture whereby *“evidence based practice is valued and expected”* (Cummings et al., 2007).

## **2.8 The countries where this study is based**

### **2.8.1 Background**

This section of the introduction aims to orientate the reader to the environments of Jordan and Malta in which the research was carried out by providing an overview of country characteristics. This research began in Jordan but due to circumstances beyond the control of the researcher, it was relocated. The study started following the outbreak of the war in Syria. As the Syrian refugee crises escalated, the focus of the Jordanian Royal Medical Service, was understandably averted to providing for the influx of refugees. The researcher did not wish to create any diversion of attention and thus it was decided it would be more appropriate, to move the study to a different location. Malta was identified as a suitable site in late 2015, with data collection commencing in March 2016.

### **2.8.2 Jordan**

#### **2.8.2.1 Geography**

Jordan is situated within the Middle East, bordered with Syria, Iraq, Israel and Saudi Arabia and covers a territory of 89,328 kilometres squared (UNDATA, 2017). It is predominately a desert plateau with temperatures that reflect this demographic of mild winters and hot summers. It is home to the Dead Sea, the lowest point on earth, resting at 431 metres below sea level (Central Intelligence Agency, 2017). The geographical site of Jordan is documented as being inhabited since the Stone Age and hosts some wonders of ancient civilisation including the UNESCO World Heritage site of Petra. Yet the Jordan of today is very much a modern land.

#### **2.8.2.2 Demographics and population**

The population of Jordan is 7,505,000 (UNDATA, 2017), although this is a variable figure due to the influx of refugees from Syria over the past few years (Central Intelligence Agency, 2017). Of this population 83 percent live in urban areas, principally because the

country is largely desert (World Health Organisation, 2016a). Nearly half of the population is concentrated in the capital city of Amman and more than 70 percent are reportedly under the age of 30 (United Nations, 2017) with 33.7% aged 0-14 years of age and in contrast over the age of 60 making up only 5.5% of the population (UNDATA, 2017). The population in Jordan has steadily increased due to a fertility rate of 3.3% (UNDATA, 2017) plus the movement of refugees driven by regional crises which has resulted in many seeking refuge in Jordan. Such mass population movement has brought with it many challenges, in particular the provision of healthcare and has impacted on the social and economic makeup of a country. Despite these challenges, the past ten years have been a period of successful educational and health reforms in Jordan (The World Bank, 2017c). One of the major challenges facing Jordan is a scarcity of water (United States Library of Congress, 2006), due to natural water sources diminishing making it one of the most water deprived nations in the world (World Health Organisation, 2017b).

The population of Jordan is mainly Arab, with a minority population (2%) of Armenian and Circassians. The official language is Arabic, spoken in various dialects. Jordan is unique within the Middle East as English is widely spoken as a second language. The main religion is Sunni Muslim with a minority population (2.2%) of Christians (Central Intelligence Agency, 2017).

Jordan is classified as an upper middle income country where life expectancy at birth is 72/76 (male/female) (World Health Organisation, 2017a), which has been steadily growing over the past decades. Neonatal mortality is recorded as being 11 deaths per 1,000 live births with under 5 mortality standing at 18 deaths per 1,000 live births (World Health Organisation, 2016a), making it one of the lowest in the region.

Tourism is essential to the Jordanian economy, with many being attracted by the large number of ancient sites and antiquities. This is of particular importance as Jordan has no natural resources and limited other exports (United Nations, 2017).

### **2.8.2.3 Healthcare provision in Jordan**

Health expenditure per capita in Jordan has been placed at being 61 US dollars (2014) (World Health Organisation, 2017a). The health workforce as per 2016 data stands at being 22.2 physicians, 20.7 nurses and midwives, 7.1 dentists and 13.5 pharmacists per 10,000 population (World Health Organisation, 2016b). This puts Jordan as a leader in workforce

per capita in the region. Healthcare in Jordan is delivered by three main providers (Al Hadidi, 2014);

1. *Public sector* which consists of the Ministry of Health (MOH), the Royal Medical Services (RMS) and two university hospitals; the Jordan University Hospital (JUH) and the King Abdullah the Second University Hospital (KAH). The MOH has overall responsibility for the maintenance of public health, supervision of public and private health sectors, the management of medical training and the maintenance of health insurance programme. Primary, secondary and tertiary care services are provided by the MOH (31 hospitals, 375 primary care centres).

The RMS is mainly responsible for the provision of secondary and tertiary care with 12 hospitals accounting for 20% of hospital beds (2013) in Jordan. The healthcare responsibilities of the RMS predominately cover military (active and retired) and security personnel and their families. Their hospitals are known for providing particularly specialised treatment and high quality care. They are also well versed in the provision of field hospitals. The university hospitals take patients from other sectors, provide care for university employees and their dependants and are teaching centres (Al Hadidi, 2014).

2. *Private sector*. Like the public sector, they provide primary, secondary and tertiary services through a number of hospitals (33% of all hospital beds), clinics and centres. They are strongly high tech focused and attract many from medical tourism (Al Hadidi, 2014).
3. *Not for profit organisations* including the United Nations Relief and Welfare Agency (UNRWA) who are responsible for the provision of all aspects of primary healthcare to Palestinian refugees and assists them in navigating to secondary and tertiary care. The King Hussein Cancer Foundation (KHCF) provides comprehensive care to Jordan but also to other countries in the Middle East (Al Hadidi, 2014).

In 2012 the WHO reported the 10 main cause of death in Jordan as being; ischaemic heart disease, stroke, diabetes mellitus, road injury, hypertensive heart disease, kidney disease, preterm birth complications, congenital anomalies, lower respiratory infections, colon and rectum cancers with the top two leading the ranking for the past 12 years (World Health Organisation, 2015a). Non communicable diseases are clearly increasing and becoming a new focus to be addressed.

As Jordan is a relatively small country, which not only has limited natural resources, it also, like many other countries has limited human resources too resulting in a shortage of healthcare professionals (Al Hadidi, 2014).

### **2.8.3 Malta**

#### **2.8.3.1 Geography**

Malta and its sister islands Gozo and Comino are situated in Southern Europe in the Mediterranean; south of Sicily and north of Libya, making up part of the Maltase Archipelago, one of the smallest Archipelagos in the world (Government Malta, 2017). The overall surface area of Malta (including all three islands) is 316 kilometres square (Government Malta, 2017). For hundreds of years Malta existed autonomously, with its own culture, language and customs. It was only with the advent of increased shipping trade that Malta found itself in the middle of a trade route (Cassar, 2002). In turn, the strategic value of Malta's position was recognised making it an important military and trading post (BBC News, 2017). The climate in Malta is affected by the Sahara desert bringing hot days and clear skies and the Atlantic creating the right conditions for rain in the winter season (Cassar, 2002).

#### **2.8.3.2 Demographics and population**

Malta's culture, cuisine and language have been shaped by historical influences largely due to its positioning in the Mediterranean (Cassar, 2002). Most notably are the early Arabic influence, Italian influence (mainly Sicilian), the order of St John (including the infamous Great Siege) and latterly a sustained British presence from 1814 when Malta became a crown colony of the British Empire, until it gained independence from Britain in 1964 (BBC News, 2017), later to become a republic in 1974 (Cassar, 2002). The main languages spoken are Maltese and English and the major religion is Roman Catholic (Government Malta, 2017).

The total population of Malta is 430,000, the highest population density in Europe (United Nations, 2016) (Azzopardi et al., 2014). Of this total population 31,446 live in Gozo or Comino, the majority of which are in Gozo as Comino is predominately uninhabited (National Statistics Office Malta, 2015). Malta is not only the largest of the three islands but houses the capital city of Valetta and is the administrative, commercial and cultural heart

of the country (Government Malta, 2017). The urban population is 95.3% (United Nations, 2016). Population growth between 2010-2015 was at an average annual rate of 0.3%, it is an aging population with approximately 25% being over the age of 60 and 14.4% between the ages of 0-14 (United Nations, 2016). Life expectancy at birth is 82/77.4 for females and males respectively (United Nations, 2016), one of the highest in Europe (Azzopardi et al., 2014). Infant mortality rate is low with 4.8 deaths per 1000 live births (United Nations, 2016) and fertility rate sits at 1.4 children per woman (2010-2015). Malta is categorised by the world bank as being a high income country (The World Bank, 2017b), reliant on tourism, information technology, remote gambling, manufacturing and finance (Azzopardi et al., 2014).

### **2.8.3.3 Healthcare provision in Malta**

In Malta, total expenditure on health per capita is 3,072 USD (World Health Organisation, 2017d) which in 2014 was 9.7% of gross domestic product (Central Intelligence Agency, 2017). The number of physicians per 1,000 population in Malta was recorded as 3.49 physicians in 2013 (Central Intelligence Agency, 2017), which meets the EU average of 3.4 physicians per 1,000 population (The Organisation for Economic Cooperation and Development (OECD), 2014). However the number of nurses and dentists do not meet the EU average and yet paediatricians, midwives and pharmacists are above (Azzopardi et al., 2014).

The WHO categorised the top 10 causes of death (2012) as being; ischaemic heart disease, stroke, trachea, bronchus, lung cancers, Alzheimer and other dementias, colon and rectum cancers, lower respiratory infection, breast cancer, pancreas cancer, diabetes mellitus, chronic obstructive pulmonary disease (World Health Organisation, 2017d). It is evident from this list that it is non-communicable diseases that are of concern with the adage of increasing levels of obesity (Azzopardi et al., 2014).

The provision of healthcare in Malta is clearly divided between the public and private sector (Azzopardi et al., 2014). Public sector healthcare is free at the point of care and is comprehensive in its provision (Azzopardi et al., 2014). The private sector which accounts for approximately thirty percent of all healthcare expenditure, is the main provider of primary care. A minority of provision is by non-governmental organisations and the church, in particular in regards to old age people homes and care homes for people with disabilities (Azzopardi et al., 2014). However, the ministry of health holds overall

responsibility for providing health services, regulations and standards (including occupational health and safety) (Azzopardi et al., 2014).

Across Malta there are five public hospitals; two for acute care and three specialised care. In addition there are two private hospitals (Government of Malta, 2017). The largest hospital in Malta is the Mater Dei hospital, an acute general teaching hospital, which opened in 2007 and is the main provider of care (Government of Malta, 2017).



## **3 Chapter Three - Methodology**

### **3.1 Introduction**

Chapter two provided a review of the area of research; models and frameworks for knowledge implementation, the role of evidence based practice and guidelines and the complexity of defining culture. As the review illustrated, much of the research within this arena is from a qualitative methodology. This chapter will therefore explore why a particular methodology and resulting methods have been employed to address the aim of the research and the research questions:

The aim of the research is to explore the appropriateness and utility of the PARIHS framework in a cross cultural context. The research questions are:

- 1) To explore the appropriateness and utility of the PARIHS framework, in the cultural translation and adaptation of an evidence based clinical practice guideline into clinical practice in the healthcare system in Malta<sup>3</sup>.
- 2) To identify the challenges and barriers to successful cultural translation and implementation to inform future cross cultural knowledge translation programmes.

The methodology will be defined and an explanation of the philosophy underpinning it will be given, whilst drawing attention to the epistemological and ontological positions. In addition, the philosophical paradigm which includes the use of case study as a methodology will be outlined. How this research uses case study and the individual methods used will be reviewed. The method of data analysis selected will also be explored.

### **3.2 The philosophy of knowledge**

This section will outline the importance of ontology, epistemology and methodology whilst identifying which approach of each will be used in this study.

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<sup>3</sup> This study began with the Royal Jordanian Medical Services, however due to unforeseen circumstances the study site had to be changed to Malta. See Chapter 2 for further explanation and background.

### 3.2.1 Ontology

Ontology refers to the beliefs that people have about reality (Denzin and Lincoln, 2011). The underlying concept of ontology pertains to the existence of the social world and how it differs from the natural world (Ormston et al., 2014). Thus, in its most basic terms ontology can be seen as the study of reality (Spencer et al., 2014). It affords one the ability to ask questions about reality such as whether society exists independently of human interpretation, whether it is an objective construct or whether social reality changes depending on the context in which it occurs (Spencer et al., 2014). There are two principal ontological positions from which these questions can be asked; **realism** and **idealism** (Ormston et al., 2014). Realism is the belief that the world exists but people's interpretations of it are different, because external reality occurs independent to beliefs (Ormston et al., 2014) indicating that there is a separation between the world and people's interpretation of it. There is a continuation of the concept of realism known as relativist ontology, which is the belief that there are a number of realities (Denzin and Lincoln, 2011).

The second position is idealism which is the view that reality cannot exist independently as it is a construct of the mind, and therefore reality is socially constructed (Ormston et al., 2014). Accordingly, reality is dependent on the mind of the individual and so reality cannot exist as an entity independent of personal belief and understanding (Ritchie et al., 2014b) i.e. everyone's interpretation of reality is different as it is dependent on these factors. In the context of research, when the world (social or natural) is observed, it is being done so through the eyes of the individual and therefore any data collated is regarded as the researcher's interpretation (Giacomini, 2010). Whether the philosophy of a researcher falls within realistic or idealistic ontology, it has an impact on their epistemological perspective, the type of methodology and the interpretative paradigm employed.

From the above, the ontological approach that is most suited to this study is relativist ontology as it encapsulates the functions of realist ontology i.e. reality is socially constructed with the additional aspect of the acknowledgement that there is more than one reality.

### 3.2.2 Epistemology

Epistemology is defined as a philosophy of knowledge (Green and Thorogood, 2014) or a "*philosophical belief system*" (Leavy, 2014) (p3). In its most basic terms it is how we know and learn (Ormston et al., 2014) and how we become knowledgeable of reality (Spencer et

al., 2014). The cornerstone of epistemology and an area that is often debated, is a consideration of how knowledge is best obtained, with the focus being an inductive and deductive approaches (Ormston et al., 2014) that is to say whether it is through a process of induction or deduction. Induction is the process whereby conclusions are made from direct observation, for example data from the field (Tracy, 2013). Induction is knowledge that has grown from ideas and theories created from the data and which can be tested by the accumulation of more data (inductive) (Bowling, 2014) and therefore knowledge is gained from the 'bottom up' (Ormston et al 2013). The converse is deduction whether a hypothesis, based on some previous knowledge, is being tested using data collated (deductive) (Bowling, 2014) whereby an idea is generated first and then evidence is used in order to confirm or refute it (Ritchie et al., 2014b) and is said to come from the 'top down' (Ormston et al., 2014) .

As ontology influences research practices, so does epistemological assumption as it affects the framing of research questions and ultimately the direction the research takes.

Therefore, like ontology it is important to understand the epistemological perspective of the researcher in order to provide an understanding of the impact this has on the research. For example, in a healthcare context epistemological assumptions can affect treatment practices and result in the application of different treatments (Green and Thorogood, 2014). Whichever view one has, or whether it is a mixture of both, it has been said that the interpretation or interrogation of data is not thought of as being performed from a totally objective standpoint as it is recognised that the researcher has views regarding the research and their own ideological standpoint and that the study has been influenced by assumptions that have been made (Ritchie et al., 2014b).

There are a number of epistemological positions including positivist and interpretative epistemology. Positivist epistemology is grounded in the existence of a reality that can be researched and understood (Denzin and Lincoln, 2011). It is linked to realist ontology (Giacomini, 2010) whereby reality is seen as being separate to human perception (Green and Thorogood, 2014). Secondly, interpretative epistemology is founded in idealist ontology (Giacomini, 2010) and aims to understand human behaviour rather than explain it. It is suitable for the study of social phenomena, the belief that the world is a place of ideas (Green and Thorogood, 2014) and that meaning comes from peoples interaction with the world around them (Lapan et al., 2012). The roots of interpretative epistemology are in the interpretive tradition; the interpretations that people make of the world, how they see

and understand it such, for example a patient's understanding of a treatment regimen (Green and Thorogood, 2014).

From outlining both positivist and interpretative epistemology, the approach suited to this study is interpretivist. This is because it regards reality as something that can be researched and understood and thus compliments the ontological approach of relativism, which states that a number of realities exist and these realities are separate to human perception.

Ultimately the approach taken is dependent on the research questions and the researcher. A researcher can never be fully impartial, there is a definite need to be clear about the defined perspective and consideration of how this will be recorded within the research (Leavy, 2014). This acknowledgement of influence extends beyond the researcher to their relationship with those being researched and the influences this can have on each other (Ritchie et al., 2014b). It is here that the concept of emic and etic may be acknowledged. For emic refers to the perspective of the participant, that is to say the interpretation of a situation by the person experiencing it (Trent and Cho, 2014), making every situation context specific (Tracy, 2013). Whereas etic is a description of the situation from a perspective put forward by the outsider (Trent and Cho, 2014).

The relationship between the researcher and those being researched and the interaction it affords, is regarded as being a fundamental part of the research process with there being either no dependency between the researcher and participant or an interplay between the two (Spencer et al., 2014). It is an area that has been debated over the years, with a conclusion that observations can never be fully objective (Denzin and Lincoln, 2011).

### **3.3 Research paradigms**

#### **3.3.1 Introduction**

Undertaking research necessitates orchestration through a clear framework of guiding elements, otherwise known as a paradigm. The paradigm is influential in all aspects of research as it operates as a guide for the direction of the research, and creates the boundaries in which work should be carried out (Leavy, 2014). The methodology to be undertaken is informed by the trilogy that is the epistemology, ontology and paradigm of a study. The research paradigm is described by *Denzin and Lincoln* (Denzin and Lincoln, 2011) (p91.) as "*a basic set of beliefs that guide action*" which encapsulate four main factors;

ethics and values (axiology), ontology, epistemology and methodology (Denzin and Lincoln, 2011), (Giacomini, 2010). There are various paradigms that help define a wide number of approaches. This diversity of paradigms has however made defining the field difficult and standardisation impossible (Spencer et al., 2014), particularly as there is now a blurring of the boundaries between each paradigm, often making it hard to define them (Denzin and Lincoln, 2011). Attention in this section will be given to three main paradigms; positivism, post-positivism and constructionism to identify which is most suitable to this study. To establish this, for each paradigm consideration will be given to their ontological and epistemological perspectives.

### **3.3.2 Positivism**

The positivist paradigm is based on the ontological perspective that there is reality which is not related to individual beliefs or assumptions and is largely based on natural science (Bowling, 2014) (Spencer et al., 2014). Positivism itself originated as a philosophy from Rene Descartes, who in the 1600's focused on the importance of objectivity, the desire to search for the truth, whilst acknowledging the need for the researcher to distance themselves from that being researched to allow for objectivity (Ritchie et al., 2014b). Positivism suggests that through a process of direct observation reality can be understood in an absolute fashion (Ormston et al., 2014) and therefore it is not interested in meaning, only that which can be observed (Bowling, 2014). From a positivist paradigm, objectivity exists from which the world can be accounted for (Denzin and Lincoln, 1998) and therefore that which is being observed and researched emulates reality (Tracy, 2013). Thus the desire to understand is supported by hypothesis generation using absolute, empirical measurement (focusing on internal and external validity) to allow for the transferability and generalisation of findings (Spencer et al., 2014) (Denzin and Lincoln, 2011) (Bowling, 2014). The perspectives which underpin a positivist paradigm are; a realist ontology, dualist / objectivist epistemology and a methodology that employs scientific methods that have internal and external validity and rigour, and statistical analysis (Lincoln et al., 2011) (Bowling, 2014) (Denzin and Lincoln, 1998).

On the basis of the above explanation of the positivist paradigm it will not be applied to this study. This is primarily because it only accounts for that which is being observed and not how that observation can be interpreted which is an important aspect of this study.

### **3.3.3 Post positivism**

Post positivism is similar to positivism as it developed from positivism (Tracy, 2013). Post positivism, is the perspective that knowledge is produced by hypothesis testing, which is evaluated against observation (Ritchie et al., 2014b) and aims to record reality as much as possible through the use of mixed methods (Denzin and Lincoln, 2011). The main differences are that the post positivist paradigm does not ascribe to the view that hypotheses are absolute, thus reality can never be anchored or fully comprehended (Denzin and Lincoln, 2011). Nor does it regard there to be full objectivity as no method of research is perfect, thus objectivity can only ever be partial (Denzin and Lincoln, 1998). Therefore to enable the collation of as much information on reality as possible a number of methods are used with a strong focus on internal and external validity (Denzin and Lincoln, 2011). In addition to this, theories are tested through a process of rigorous testing with a view that failure shows an untrue hypothesis (Giacomini, 2010). Aspects of validity and reliability are central factors as is the acceptance of bias, that is to say, it is unavoidable (Spencer et al., 2014). Due to the latter, much effort is put into ways in which bias can be lessened and controlled, particularly through the introduction of processes such as triangulation and control groups (Spencer et al., 2014). In conjunction with the desire to lessen bias, the researcher takes the position of an objective standpoint and cannot be involved with study participants (Tracy, 2013). Like positivism, post-positivism is related to a realist ontology and an objectivist/dualist epistemology akin to positivism (Lincoln et al., 2011). Research methodologies related to post positivism are those which are systematic, experimental and encourage rigour (Denzin and Lincoln, 2011).

As post positivism is an extension of positivism with the added aspect of rigid hypothesis testing, it is regarded as unsuitable for this study whereby the research questions of exploration and identification, do not fit with this strict paradigm.

### **3.3.4 Constructivism**

Constructivism, as perhaps the name suggests, is the view that humans are actively involved in constructing knowledge (Ormston et al., 2014). It is therefore based on the premise that what is understood to be reality is informed through components such as “social interactions, relationship and experience”(Spencer et al., 2014 -b)(p87). Thus a person’s knowledge and understanding are social constructs formed and expressed through these components (Tracy, 2013). Identity is seen as a social construct which

continuously morphs as it is responsive to context and how a person thinks others perceive them (Spencer et al., 2014 -b). An understanding of such phenomena, is achieved through an in-depth description of the phenomena (Taylor, 2013). The constructivist paradigm, concurs with a focus on the transferability of data and credibility, replacing validity with trustworthiness and authenticity (Denzin and Lincoln, 2011). Methodologies include ethnography, phenomenology, narrative inquiry, case story and historical research (Lapan et al., 2012), which can be regarded as being more dialectic fits with the paradigm (Denzin and Lincoln, 2011). It also corresponds with a relativist ontology (the notion that there are multiple realities) and subjectivist epistemology (the researcher and the subject create understandings) (Denzin and Lincoln, 1998). In constructivism, reality sits at the opposite end of the spectrum to positivism as reality is regarded as being the end product of 'human process' (Green and Thorogood, 2014).

Having identified positivism and post positivism not fitting the attributes of this study, it is concluded that constructivism is most suitable. This is largely due to its focus on people being actively involved in the social construction of knowledge, thus taking into consideration context and culture amongst other influences.

### **3.3.5 Constructivist paradigm in this study**

Thus far it has been established that the view of the researcher regarding reality (ontology) and acquisition of knowledge (epistemology) impact on the choices of method of enquiry. These together with an understanding of the influence of various paradigms inform the methodology chosen. This study focuses on identifying the cross cultural utility of the PARIHS framework. To garner a solid understanding of its cross cultural utility, an in-depth understanding of the opinions and practices of healthcare professionals is needed. The pursuit of a comprehensive insight is suited to constructivism whereby the role of the individual is paramount to the construction of knowledge which informs reality (Ormston et al., 2014). The interest in and recognition of culture and context within this research, is harnessed by the constructivist view that identity is a social construct which continuously morphs as it is responsive to context (Spencer et al., 2014). Acknowledgement of the importance of social interaction, its link to the relativist ontological view that there is more than one reality and this reality is produced by humans and all that they encapsulate, substantiates its use. In keeping with the constructivist paradigm, a naturalistic methodology (a methodology whereby the study is carried out in the natural setting of the participants) (Skeggs, 2013) will be used.

## 3.4 Methodology

### 3.4.1 Introduction

As with many concepts, methodology is a difficult area to define, particularly when one considers that meaning has different relevance in different settings (Denzin and Lincoln, 2011). Nevertheless, from the available descriptions, the following two descriptions identify that the aim of the application of methodology is to determine how to gain knowledge, illustrating its purpose and use;

*“The best means for gaining knowledge about the world”* (Denzin and Lincoln, 2011)(p91)

*“A way of thinking about and studying social phenomena”* (Corbin and Strauss, 2015) (p1) .

The various methodologies of qualitative research can be regarded as a bricolage, e.g. something that has been created from a range of tools and methods (Denzin and Lincoln, 1998). This illustrates that the methodology selected for a specific research project is affected by numerous factors including the aims of the research, the research funding, the participants to be involved and the personal and academic background of the researcher (Ritchie et al., 2014b) (Denzin and Lincoln, 2011). Of a more fundamental importance are the influences of ontology; the beliefs people have about what makes reality (Giacomini, 2010)(128), epistemology the way in which people learn about reality (Ritchie et al., 2014b), the paradigm (research guide) chosen and axiology, the values and assumptions held by the researcher (Spencer et al., 2014). Denzin and Lincoln (Denzin and Lincoln, 2011) conceptualise this by regarding ontology as the framework of the research, epistemology as the guide for the questions to be asked and methodology as the way in which the research is examined. The three elements; paradigm, ontology and epistemology may be regarded as being the ‘philosophical’ structure and overarching guides of research (Leavy, 2014).

The philosophical structure underpinning this study has been defined. It is therefore now appropriate to identify a methodology which will work in harmony with the philosophy chosen. As stated, methodology provides the guidance for research design with methods being the individual research practice or procedures that are used to implement the methodology (Giacomini, 2010). Methodologies fall within the two categories of qualitative and quantitative methodology which can either be used alone or in combination with each other. Traditionally there has been opposition between qualitative methodology



and quantitative research (Lapan et al., 2012) (Denzin and Lincoln, 2011). Nevertheless, today they are viewed more as complementary of each other as research collaborations increase and the disciplines from which people come begin to mix (Giacomini, 2010). Historically qualitative and quantitative methods were regarded as being distinctly opposing paradigms, and thus it was thought that they could not be used together, however over time views have changed and there are now many mixed methods studies (O'Cathain, 2010).

This section will take into account quantitative and qualitative methodology, methodological influences and an explanation of and reasoning for the methodology chosen.

### **3.4.2 Quantitative research**

As the name suggests, the focus of quantitative research is on 'quantities' and the identification of causative relationships, prevalence and hypothesis testing (Bowling, 2014). Quantitative research is traditionally aligned with a positivist paradigm whereby knowledge is absolute, is deductive, variables can be controlled (Taylor and Francis, 2013). Differences are measured empirically in a quantifiable, numeric way, structured by a predetermined hypothesis to be tested (Cunningham et al., 2013). The application of quantitative research is suitable for situations (research questions) where some knowledge already exists and data can be collected in a standard format such as in randomised control trials, cohort studies and surveys (Bowling, 2014).

### **3.4.3 Qualitative research**

The practice of qualitative research is defined by three processes; ontology (being), epistemology (knowledge) and methodology (inquiry) (Denzin and Lincoln, 1998) and is noted as *"exploring the meaning of human experiences"* (Taylor and Francis, 2013) (p3). Denzin and Lincoln (Denzin and Lincoln, 2011) (p3) propose that *"qualitative research is a situated activity that locates the observer in the world. It consists of a set of interpretative material practices that make the world visible ... qualitative research involves an interpretative naturalistic approach to the world"*. The intention of qualitative research is to understand how people make sense of the world and the meaning that they attribute to their experiences (Pope and Mays, 2006). Qualitative research thus seeks to find meaning in the world through being a part of it rather than detached from it and emphasises the

importance of context (Lapan et al., 2012). Understanding meaning within context is sought through the analysis of experiences, interactions, communications and documentation (Flick and Metzler, 2014). In particular, this exploration is through language as this is the medium in which people predominately express themselves (Taylor and Francis, 2013). Hence, qualitative research is regarded as being inductive as theories emerge from the data.

Qualitative research is about being immersed in the situation (at varying levels), being in the context and making sense of what is observed and recorded (Tracy, 2013). Because of the situational aspect of qualitative research, it allows access to be given to cultural aspects that may not materialise if the research was not carried out face to face (Tracy, 2013). Data generation and collection work occurs with the context in which they are carried out and are therefore sensitive to it (Ormston et al., 2014). In keeping with this, qualitative researchers are regarded as being more able to ascertain the perspective of the individual because of the methods of data collection capture such as interviews (Denzin and Lincoln, 1998). These experiences of data collection allow theories to arise from the data collated or from existing theory (Cunningham et al., 2013). As a methodology, qualitative research is used across a variety of disciplines, with a number of different approaches (Ritchie et al., 2014b).

Having outlined the different perspectives of quantitative and qualitative research methodology, this study will be carried out using a qualitative research methodology. This is principally because the study is not testing hypothesis looking for causative relationships but seeking to understand the appropriateness of the PARIHS framework in a cross cultural setting whilst identifying the challenges and barriers to the implementation of knowledge cross culturally. The following looks at some of the components of qualitative research in greater details to inform which methodology will be used for this study.

#### **3.4.4 Consideration of qualitative methodologies**

In sum, it has been established that this research will use a constructivist paradigm (people are involved in constructing knowledge), with a subjectivist epistemology (the subject and researcher create understanding), a relativist ontology (people interpret the world differently) and a qualitative methodology. Thus qualitative methodologies; grounded theory, ethnography and case study will be outlined, following which the type of

methodology to be used in this study will be identified, outlining the reasons why it was chosen. It will conclude with the methods used within the methodology being outlined.

#### **3.4.4.1 Grounded theory**

Grounded theory is a qualitative methodology of data collection and analysis, through which *“theoretical constructs (are) derived from qualitative analysis of data”* (Corbin and Strauss, 2015)(p1). It has been in use since it was first conceptualised in 1967 (Strauss and Corbin 1998) and has developed over the past fifty years with separate schools of thought emerging as to what constitutes grounded theory (Pawluch and Neiterman, 2010). Despite differing views, grounded theory remains an inductive theory which emphasises the emergence of theory from data, and outlines a process for data analysis (Licqurish and Seibold, 2011). Within grounded theory data collection should be systematic and a wide range of methods should be used (Bowling, 2014) such as pre and post interviews and observational data (Licqurish and Seibold, 2011). Data collection and analysis in grounded theory are closely linked and occur simultaneously (Bryant, 2014). This simultaneous relationship is a defining feature of grounded theory as it is regarded as being ‘cyclical and iterative’ (Pope et al., 2006) (p70), for as a theory arises from the data it is retested with new data until a point of data saturation, when no more new concepts are identified, has been achieved (Pope et al., 2006).

#### **3.4.4.2 Ethnography**

Ethnography as a methodology developed from anthropology and a quest to understand cultures and societies (Francis, 2013). Over time, a number of different types of ethnography have emerged (Rock, 2013), and therefore there is not one distinct paradigm or epistemology that can be applied to ethnography as it can be positivist or interpretivist (Harrison et al., 2013). However, the intention is; to provide researchers with a way to study cultures in depth (Francis, 2013). Studying cultures in depth is the essence of ethnography, which is underpinned by cultural immersion (experiencing the culture first hand) (Atkinson et al., 2013) making ethnography an intensive study over time. Other specific features of ethnography are that the researcher is central to the research process and data analysis is seen as a cyclical approach (Atkinson et al., 2013) (Francis, 2013). It is said that through being immersed in a culture people have the opportunity to see and understand how cultures regard themselves and the wider world (Francis, 2013). Ethnography recognises the “role of culture and socialisation in shaping social realities”

(Harrison, 2014) p11 and can thus be interpreted as an analysis of society (Armstrong, 2008).

Data collection in ethnography is led mainly by participant observation although this is coupled with other methods of data collection (Atkinson et al., 2013). Other techniques include, interviews, focus groups, field notes and the review of documentation (Harrison, 2014). However, traditional ethnography is principally a report of what has been observed (De Chesnay, 2015).

#### **3.4.4.3 Case study**

Case study is a methodology which has been increasingly applied to notoriously difficult areas to study and need approaches that allow for different perspectives. The exponential growth in the healthcare industry, such as ever advancing technologies, management structures and patient expectations has resulted in numerous challenges for healthcare organisations, in particular finding ways in which these changes can be implemented and outcomes measured (Caronna, 2010). Case study is one such perspective (Caronna, 2010). Case study as a research methodology has become a key approach to research as it is a means of developing an in-depth understanding of a single unique case, for which a story is told. What is being observed or studied is being done so in real time, in real life and in situ (Simons, 2014) (Yin, 2012). The main aim of a case study is to explore what is referred to as a single case, whether this is a system, a place or a person (Simons, 2009). A qualitative case study allows for the collation of participant views in context, and an insight into the way in which they construct their world. There are a number of definitions of case study, (Simons, 2014) but (Yin, 2012) clearly depicts four types of case study; a single or multiple (more than one case study) holistic case study, which has an organisational focus or a single or multiple embedded case study which has a people focus.

Whichever type chosen, there is a level of flexibility in case study research as it can be purely qualitative or mixed method, can be from different epistemologies such as constructionist and it is adaptable and applicable in varying contexts (Simons, 2014). This level of flexibility is also not just limited to the research methods chosen but also to the time frame, style of analysis and reporting (Simons, 2014). Moreover, it is suggested that a robust case study is one which uses a mixture of data sources (Yin, 2012) thus a number of methods can be used to undertake a case study allowing for a multifaceted investigation into the case and the actual context (Simons, 2009).

There is a well-defined guide to employing a case study approach with advice on certain steps which should be followed when planning for a case study. These steps include the identification of; the research topic to provide a focus for the study, exactly what is being studied e.g. a department, a ward, a team or a system, what the case is made up of and what the boundaries are (Simons, 2014) (Yin, 2012) . Whilst there is some debate as to whether it is necessary or appropriate to define the boundaries of the case at the beginning of the study, it is worth undertaking as it encourages awareness of the fact these boundaries may change once the research is being conducted in the field (Simons, 2009). Following this, it is advisable to create a clear link to the relevant literature or policy as by doing so, not only is the study more robust but it is said to increase the generalizability of the results (Yin, 2012). Finally the reviewer selects the right case study design (from the four previously outlined) (Yin, 2012). Once these steps have been followed then an appropriate protocol to guide the work can be produced.

#### **3.4.5 Chosen methodology for this study**

Following the description of these possible qualitative approaches, case study methodology was identified as being the most suitable for the aims of this research. Grounded theory was regarded as inappropriate because of an over reliance on creating and retesting theories, for the aim of this research was to ascertain the utility of the PARIHS framework and identify barriers and facilitators to knowledge implementation as opposed to theory testing. Ethnography is also based on a test / retest approach and focuses on studying cultures in depth which is not the purpose of this study. The aim of this study is to evaluate the function of the PARIHS framework cross culturally thus looking at the influence of culture. In case study,

Case study not only uses a variety of methods which allow for quality through the triangulation of data (Roulston, 2010) but also an in- depth understanding of the area being researched. Using a range of methods lets different perspectives be recorded, allowing for a detailed exploration and understanding of factors such as successes and barriers in healthcare, prompted by real time actions and a whole story to be told (Simons, 2014) (Caronna, 2010). The opportunity to garner different understanding and attitudes towards enablers and barriers is integral to this study. Furthermore, in case study 'context' (i.e. political, organisational, cultural or social) has a lead role to play as it is recognised that context is integral to shaping the case (Mabry, 2008). This is particularly key to this study in which the context is a central element. Within the context of this study, the case is defined

as; the exploration of the appropriateness and utility of the PARIHS framework, within the context of the main hospital in Malta. It is an embedded (data from more than one group of people) single case (one organisation e.g. a specific hospital) study design and is informed by a theory of knowledge implementation, the Promoting Action on Research Implementation in Health Services (Kitson Alison. L et al., 2008). To achieve this, the participants' views, thoughts and experiences are sought, as are the identification of challenges and barriers to cultural translation and knowledge implementation, following a practical application of guideline development. This reasoning is compatible with the constructivist paradigm of reality being informed by social interaction (Spencer et al., 2014), a realist ontology and interpretivist epistemology.

As identified, the context for this study is the major hospital in Malta, which the researcher will visit on a number of occasions. Being able to collate data without having to maintain an in situ presence is in keeping with case study methodology, for although data is collated from a variety of sources it does not necessitate the researcher having to be immersed in a setting (Sofaer, 1999), allowing for observations to be carried out over short periods (Caronna, 2010). This allows the researcher to gather as much information as possible over a period of time about the area of study, whether that is an individual, group, organisation or culture (Taylor and Francis, 2013).

There has been criticism of case study, primarily that it is difficult to make generalisations from the data (Taylor and Francis, 2013). However, one needs to be mindful of the fact that generalisation here is not being applied to the context, but rather the ideas, theories and process that are emulating from the context, which can then be applied to inform practice (Simons, 2014) (Simons, 2009).

Case study research methodology has frequently been used in healthcare including in studies of knowledge implementation. For example, in a study protocol by (Grove et al., 2015), they propose the use of a multiple case study, using interviews, document analysis and observation looking at the implementation of elective orthopaedic surgery guidance. They identify that the data collated will be reviewed to ascertain "*values, beliefs and norms*" regarding the use of evidence and clinical guidelines (Grove et al., 2015). An additional study by Conklin et al (Conklin et al., 2015) used a multiple case study to identify the processes involved in guideline development and implementation in context. In a study looking at the implementation of evidence based practice to identify key elements of context and processes Stetler et al (Stetler et al., 2009b) used a mixed method explanatory

case study, using interviews, observations, document review, field notes and surveys. It is an illustration of the variety of data that can be collated. These examples are not only illustrations of the use of case study but also how case study affords the researchers to have aggregate and individual data (Conklin et al., 2015).

### **3.4.6 Rigour**

Rigour in qualitative research pertains to the way in which research is carried out from beginning to end; from planning, to data collection to analysis (Bowling, 2014). Whilst there may be debate over how to assess rigour and reliability (Mays and Pope, 2007), the intention of it is to demonstrate validity of the data. Aspects integral to ensuring rigour include being explicit in showing the methods of data collection and analysis used; recording how the research is conducted; encouraging the researcher to keep a diary of their experiences and thoughts (reflexivity, which is further outlined below); where possible, have a co-researcher to work with and cross interpret data (Bowling, 2014). Rigour is associated with validity, which emphasises the importance on honesty and accurate representation (Holloway, 2005) which can be done through;

- a) Triangulation –Denzin and Lincoln (Denzin and Lincoln, 1998) identified four types of triangulation; data triangulation, whereby data is compared from a number of sources. Different methods can be used for the collation of the data (Mays and Pope, 2007); investigator triangulation, as more than one researcher is used to collate and interpret data; theory triangulation, data is looked at using a different perspective to understand it; and methodological triangulation where more than one method is used to address or understand a problem.
- b) Respondent validation – the practice of cross checking participant contributions by giving participants the opportunity to review their contributions (Lewis et al., 2014).
- c) Transparency has a central focus too as reproduction of data can be difficult therefore it is important to identify all steps taken. This can be demonstrated through an audit trail, a clear record of all that has occurred during the research process, exposing the methods of data collection and analysis (Holloway, 2005) (Mays and Pope, 2007).

As established, rigour is about the integrity of the data, and within qualitative research there are different views on how this can be demonstrated, with a more traditional model,

derived from quantitative research described above. Holloway and Galvin (Holloway and Galvin, 2017) outlined a framework for establishing the 'trustworthiness', of qualitative research. Trustworthiness is an alternative term to rigour, as proposed by Guba and Lincoln (Guba and Lincoln, 1989). According to Holloway and Galvin (Holloway and Galvin, 2017) there are five components to be addressed:

1. Dependability –refers to exactness and uniformity of findings. Enough information is given, for example an audit trail, to allow a researcher to undertake the same process of data collection and analysis.
2. Credibility – focuses on the insights of participants corroborating with findings.
3. Transferability – understanding that the findings of a study have relevance outside of the study context and therefore can be applied to a similar context.
4. Confirmability - review of whether the objectives have been achieved through the research. To do this there must be the ability to track data from where it emulated i.e. through an audit trail.
5. Authenticity – relates to the employment of suitable strategies which allow the researcher to report the views of participants in a fair way. Original work is an outcome of the study.

These five aspects will be considered and reflected upon continuously throughout the study to ensure trustworthiness.

### **3.4.7 Reflexivity**

The essence of who you are shapes your approach to everything, including research (Tracy, 2013). Reflexivity therefore is a recognition of this through the identification and acknowledgement of the symbiotic relationship of the researcher and the research process (Mays and Pope, 2007). Thus it is a consideration of their experiences, understanding and views (Tracy, 2013). The process of reflexivity which documents many aspects such as; difficult encounters, events that were not planned for, information that was unexpected, amounts to a critical analysis of the researcher and all that is encountered (Holloway, 2005) (Green and Thorogood, 2014). It is a practise which identifies the researcher within the larger research process (Holloway and Wheeler, 2013). This practice takes on different forms in quantitative and qualitative research. That is to say in the former it may be regarded as an exercise of minimising and accounting for biases and in the latter it is a process of critical reflection of the research process, of which the researcher is an integral



part (Flick and Metzler, 2014), and ensuring this is recorded. In doing so, acknowledgement should be given to factors such as the socio political context, the motivation behind certain questions and current health policy. There is also a need for personal reflexivity, i.e. reflection by the researcher of their role and the influence this has on the entire research process and data generation taking into consideration factors such as gender, soci-economic status, whether they were an insider or outsider of the community (Green and Thorogood, 2014).

## 4 Chapter Four - Methods

### 4.1 Introduction

Method selection is informed by the methodology of the research and are the ways in which data is collected such as focus groups, interviews and observation (Leavy, 2014). As the methodology identified for use in this study is case study, the use of more than one method is necessitated. For a case study or any other methodology that requires more than one method, the methods chosen should work in synchrony with each other, increasing external validity (Bowling, 2014) or rather, for the purpose of this study transferability. For the purpose of this study, the methods; focus group, semi structured interview and observation were chosen as they will work in harmony with each other to facilitate the collation of data to address the research questions; the exploration of the appropriateness and utility of the PARIHS framework, in the cultural translation and adaptation of an evidence based clinical practice guideline into clinical practice in the healthcare system in Malta; the identification of the challenges and barriers to successful cultural translation and implementation to inform future cross cultural knowledge translation programmes.

This section will provide an overview of these three methods to gain an understanding of their use and how they will be applied to this study. Section 3.10 will focus on how these methods were used in this study.

### 4.2 Focus group

*“Collective conversations or group interviews”* providing a privileged opportunity to observe discourse akin to that which happens in everyday life, is how (Kamberelis and Dimitriadis, 2011) (p545) describe a focus group. Although this description accurately refers to the discourse that is experienced, (Barbour, 2007) emphasises that the term ‘focus group’ is often inappropriately interchanged with ‘group interview’ or ‘focus group interview’ as the purpose is not to interview participants but to facilitate a group discussion and gain an understanding of the thoughts of participants in regards to a specific topic or event (Holloway and Wheeler, 2009). Thus a focus group may be regarded as a ‘methodological strategy’ (Barbour, 2010) (p318) which is used in various forms to explore concepts, across a number of settings including the healthcare sector (Kamberelis and Dimitriadis, 2014).

#### **4.2.1 How focus groups are used**

Some of the diversity and flexibility in the way in which focus groups can be utilised as a method of data collection, can be seen in the following examples. McKillop et al (2011) ran a number of focus groups in New Zealand to gather the “perspective and experiences” (McKillop et al., 2011) (p163) of participants of using a cardiovascular risk guideline. Likewise Straus (Straus et al., 2013), used focus groups as part of their strategy to explore the barriers and enablers related to the use of guidelines on postpartum haemorrhage in Kosovo. In a UK study looking at the development of an intervention to increase the use of a viral encephalitis guideline, Backman et al (2015), used focus groups not only as a means of piloting concepts to be used for interviews, but to see whether the focus group would be the right forum in which to collate this data (Backman et al., 2015). In the United States, as part of a mixed methods iterative process, Guerrero et al (2016), used focus groups to collect data about the experiences of participants of implementation strategies used for the implementation of evidence based practice (Guerrero et al., 2016).

#### **4.2.2 Main functions of focus groups**

Focus groups have been identified as having three main functions; group participation with an aim to discuss issues relative to the interests of the group, a group discussion whereby the motivation is to create change for a set of stakeholders and lastly a group where the focus is to gather views from individuals about specific topics relating to them individually (Kamberelis and Dimitriadis, 2011). Thus, the function is dependent on the circumstance and purpose for which a focus group is used. It is perhaps the versatility of its functions that explains why the usage and popularity of conducting focus groups has increased within healthcare over recent decades (Barbour, 2007). Within the parameters of this case study, focus groups will be used to ascertain health professionals’ understanding and views about evidence based practice, (in particular clinical guidelines) and to provide an initial exploration and insights into participants’ understanding of how knowledge translation is perceived in the Jordanian and Maltese context and their current views and understanding of translation practice.

A focus group may be regarded as an opportunity to collate data from a number of people, eliciting data that may not materialise through independent interviewing because of the interactive group dynamics fuelled by social interaction (Kamberelis and Dimitriadis, 2014). It is a mechanism through which one can engage with a number of people at the same

time, however sometimes this advantage is regarded as a way of undertaking research quickly or as a time saving method of data collection or interpretation, yet it is not (Barbour, 2007). On the contrary, more and often richer data can be produced because of the dynamics of the focus group with it being an empowering experience. In some circumstances, the feeling of being part of a group and the support that this affords, can result in the provision of a collective voice, (Kamberelis and Dimitriadis, 2014), which is of particular use if the purpose is to establish how a concept is developed or perceived by a group. This latter point is particularly useful in the context of this study whereby the researcher wishes to ascertain the knowledge, views and attitudes of participants to the use of evidence based medicine.

Furthermore, focus groups can allow access to marginalised populations such as; those who may not be comfortable in one to one situations, people from different cultural groups and those whom have previously not been given a platform on which to express their views (Barbour, 2007). In the context of this study, this may have resonance with the participants of these focus groups in regards to cultural norms within an organisational context e.g. the position of junior and senior healthcare professionals and the influence of societal cultural norms such as the interactions between men and women. However, being a part of a group and the workings of group dynamics does not always create a positive effect as it can result in social desirability bias, whereby participants may be in agreement with each other as they do not wish to share their own doubts, as experienced by (Backman et al., 2015), who decided their population sample would provide more meaningful data if they were interviewed on a one to one basis. Equally, participants may find the experience intimidating or may feel inferior to their peers as they may feel inhibited to share in a group environment with the potential for group dynamics squashing discussion (Holloway and Wheeler, 2009). Potential issues such as these were dealt with in this study by creating an atmosphere of equality and worth from the beginning by explaining why the views and thoughts of all participants hold equal importance; encouraging inclusion of all in any focus group activities; giving people the opportunity to talk to the researcher separately if this is more comfortable.

The nature of being in a group can result in inconsistencies arising between the group and on an individual basis, particularly as participants become influenced by the situation and by the thoughts and ideas of other members of the group (Barbour, 2007). Yet, the social interaction that takes place is key, with participants responding not only to the facilitator

but to each other and providing the opportunity for the researcher to prompt (Holloway and Wheeler, 2009). This results in not only information from the group but the researcher observing the complexity of interactions, possible discrepancies between participants and group dynamics, the latter of which are of importance as they are an aid to interpreting the spoken word (Kamberelis and Dimitriadis, 2011).

Therefore, one can identify two clear aspects of focus group data; the recorded word and the observed dynamics. Interactions and group dynamics will be recorded by the researcher in this study, by noting them as they are observed. When transcribing and analysing the data, these observations will be used as an aide memoir. For clarification about any interactions that may seem culturally different, clarification will be sought from a Jordanian or Maltese representative to ensure accuracy of reporting. Although, focus groups are used to gain insight into the verbal and behavioural workings of a particular group, both Barbour and Kamberelis (Barbour, 2007) (Kamberelis and Dimitriadis, 2014) urge that they should be used with caution as their use in determining individual attitudes or beliefs can be restricted. However, the individual can be considered when analysing data in regards to their interaction with the group and their participation within the discussion (Barbour, 2007).

#### **4.2.3 Focus groups: areas for consideration**

The benefits of holding focus groups have been outlined in the preceding discussion, and how they will be applied to this study. However there are aspects that need to be considered when undertaking focus groups as they are not necessarily easy situations to facilitate and manage (Holloway and Wheeler, 2009). For example, there is the possibility that; the participants take over the group, there is dominance of certain members and participants regard contributing as being in agreement with one another (Kamberelis and Dimitriadis, 2014) (Holloway and Wheeler, 2009). These examples indicate the importance of establishing awareness and understanding of the difficulties that one may encounter and knowledge about how to handle such situations to keep the conversations flowing. Some recommend that it is prudent, prior to embarking on a focus group, to undertake training or advancing ones understanding in group facilitation (Kamberelis and Dimitriadis, 2014). With this in mind the researcher who will be holding the focus groups is experienced in facilitating group discussions, has sought advice from others who are more experienced and has further enhanced their knowledge by reading key text such as Barbour (Barbour, 2007) .

Practical considerations also need to be made such as who will record the key points of the discussion as the focus group is facilitated by the researcher. It is helpful if possible to have another person to help during the focus group, who can make notes regarding the discussion (Holloway and Wheeler, 2009). As with other methods, within a focus group, the researcher has an impact and influence on the discussion. This influence needs to be acknowledged and accounted for (Barbour, 2007) during the process of running the group and in writing up the data and shall be annotated in this study. Yet, such researcher involvement allows the researcher to pick up on possible contradictions and group dynamics, which, as already established are equally important to report, as well as the content of what is being said (Kamberelis and Dimitriadis, 2014).

#### **4.2.4 Application of focus groups to this study**

In the context of this case study, focus group has been identified as a suitable method in providing an understanding of the case. The use of focus groups in this case study is in keeping with the third function, as identified by Kamberelis and Dimitriadis (2014); a means of eliciting the views and understanding of individuals about a specific topic which relates to them individually and collectively (Kamberelis and Dimitriadis, 2014). The topic this relates to in this study is evidence based practice, what it means to them, what underpins healthcare practice in the country in which they work and how evidence is used in the healthcare settings in which they work. In addressing these areas, further insight into the three overarching elements of the PARIHS framework; evidence, context and facilitation will also be explored to help establish whether they are aspects that have resonance within the specific culture. This is therefore directly related to whether the PARIHS framework has cross cultural utility. Gaining a further understanding of the thoughts and views of participants through the collated data, both verbal and observed, will inform and shape the questions to be used in semi structured pre and post interviews to be held with members of the guideline development group.

In addition, the focus group will be used as a means to developing the researcher's knowledge and understanding of not only the topic area (Barbour, 2007) participants fluency and ease in the use of English. Not only does consideration need to be given to the focus groups not being held in the indigenous language of the group but further consideration needs to be paid to the cross cultural dynamics of the researcher and the participants, the dynamics of multi-professional health professionals, status and gender. The researcher will need to be observant and flexible to the needs of the group e.g. altering

language for simplification, repeating questions and seeking clarification if needed. The focus group will be limited in size in accordance with Barbour (2013) who suggests that eight is the optimum number of people, to allow for all participants in the focus group to be heard and a range of views to be elicited (Barbour, 2007).

#### **4.2.5 Cultural awareness and focus groups**

To safeguard against acting culturally inappropriately or to lessen the impact of being an 'outsider' Colucci (2008) identified aspects to take into consideration when planning and carrying out focus groups cross culturally;

- Be aware of cultural behaviours; may need to demonstrate that it is ok to disagree with each other, or that talking over one other loudly may be acceptable in some cultures but not others.
- Meeting as a group may be culturally inappropriate or insensitive. This would need to be ascertained prior to holding the group.
- Consider that there may be an element of mistrust of strangers.
- Arrangements for the focus group need to be appropriate. For example, appropriate refreshments should be provided and it is important to hold the focus group at a time that is acceptable to participants e.g. not during prayer time or siesta.
- Learning about the culture where the focus is to be held cannot be underestimated. (Colucci, 2008)

These factors will be carefully considered in the context of this case study as the focus groups will be undertaken in different cultures to the researcher's indigenous culture, and they will also be facilitated by someone who is not a community member. Potentially, the groups' unfamiliarity with the situation, and an unknown researcher and facilitator could impact on the function of the focus groups either positively or negatively. For example, the fact that the situation is new and the researcher is unconnected to the participants may inspire people to be open and free with their participations or it may have the converse effect. It is intended that through the adoption of the above strategies in this study, any cultural barriers will be minimised. Careful field notes will be taken to record these factors.

## 4.3 Interviewing

Interviewing, as a means of recording and elucidating information from people, dates back centuries with records showing its use in the Peloponnesian wars in Ancient Greece (Brinkmann, 2014). It is a practice that has continued and developed since creating a range of interview techniques from those that are totally structured and akin to questionnaires, to those that are completely unstructured and more informal (Kelly, 2010). It has been said that as conversing is what people do naturally to gain an understanding about each other and the world around them, interviewing in its most general sense is perhaps the next step to conversing (Brinkmann, 2014). Yet whilst an interview may be a natural next step, it is not actually a completely free ranging conversation, as it is often a guided process, during which the participant provides information as a response to the interviewer (Holloway and Wheeler, 2013). Caution needs to be exercised over comparing qualitative interviewing to conversation and oversimplifying the process as it is not just a conversation but a well-planned process (Packer, 2011), designed to answer a specific research question. In keeping with this and as an insight into its complexity, because people know how to converse it does not mean they necessarily have the skills to carry out a qualitative interview and ask questions that will result in appropriate data collection (Brinkmann, 2014). In an interview it is the interaction and inquiry which results in data production (Kelly, 2010). In essence, a qualitative interview is a method used for the production of knowledge through an interviewee's account of how they perceive the world and act within it (Brinkmann, 2014) and it is used to *"gain access to the knowledge, experience and perspectives"* of those being interviewed (Kelly, 2010) (p309). This is further discussed below as are the different types of qualitative interviewing.

### 4.3.1 Qualitative interviewing

Qualitative interviewing, the term used for different types of interviewing, aims to collect qualitative data by inviting people to talk (Josselson, 2013). It is regarded as being a pivotal method of data collection (Brinkmann, 2014) and has increased in popularity, particularly in healthcare over the past decade, driven by the understanding that data from qualitative interviews can contribute to the improvement of patient care (Kelly, 2010).

Interviews have frequently been used for the assessment of knowledge translation projects. The following are examples of how interviews have been applied, as a process of understanding how interviews can be used and which type can be best applied to this



study. Ekirapa-Kiracho et al (2014) proposed the use of pre and post structured interviews as part of a mixed methods approach to evaluating a health systems knowledge translation network for Africa (Ekirapa-Kiracho et al., 2014). Interviews were specifically chosen to evaluate the effect of knowledge translation on the project partners and those involved in research orientated activity. In a multiple case study protocol, designed to develop and implement three deprescribing guidelines, semi structured interviews were proposed as a method of data collection in all three phases of the study with various participants (in some cases pre and post development) including members of guideline development teams (Conklin et al., 2015). In a study protocol by Grove et al (2015) looking at barriers and facilitators to guideline implementation amongst orthopaedic surgeons, interviews are to be used to ascertain the views of the participants towards the use of clinical guidelines (Grove et al., 2015). Interviews were employed as the chosen method of data collection by van der Zipp et al (2016) and were successfully applied to understand further the role of leadership in the implementation of evidence, in particular the relationship between clinical and managerial leaders (van der Zijpp et al., 2016). They highlighted communication as a critical component for success.

A further example is a study carried out in Iran where a series of semi-structured interviews were used to identify factors that influence evidence based health policy documentation (Imani-Nasab et al., 2014). Semi structured interviews were also used by Chimeddamba et al (2015) in a qualitative study looking at the perspectives and experiences of primary care providers in regards to the implementation of clinical guidelines in Mongolia (Chimeddamba et al., 2015). The data revealed that successful implementation of clinical guidelines needs to be supported by adequate dissemination and implementation strategies. In a final example, Ellen et al (2014) used semi-structured telephone interviews with a selection of staff groups, to successfully ascertain the barriers and facilitators to the implementation of supports for evidence informed decision making and what can be done to facilitate implementation of evidence informed decision making (Ellen et al., 2014).

#### **4.3.2 Types of qualitative interviews**

There are different types of qualitative interviews which fall mainly into three wide categories; structured interviews, unstructured interviews and semi-structured interviews, (Packer, 2011, Brinkmann, 2014) and which can be applied across the range of qualitative approaches (Packer, 2011). The type of interview used is dependent on the research question and the type of data one intends to collate. Through reviewing these three types,

a decision will be made as to which is most suitable for this study, whereby the intention is to explore and understand whether; the PARIHS framework has cross cultural applicability; the barriers and facilitators to implementing knowledge into practice and the process of guideline development. The interviews will be with the people with whom the PARIHS framework has been used as it is their views, thoughts and understanding that is needed.

#### **4.3.3 Structured and un-structured interviews**

Structured interviews mainly take the form of surveys or interviews which are standardised in the way in which the questions are written and asked (Kelly, 2010), the main aim of which is to gain responses that fit within particular categories (Packer, 2011). Generally, in qualitative research, structured interviews are not used, primarily because their rigid structure is seen as stifling the free flow of data (Holloway and Wheeler, 2013). With this in mind, it is clear that this form of interview is not appropriate for this study as it is important for the interviewees' responses not to be curtailed by the structure of the questions, to enable a thorough exploration of the topic.

At the other end of the spectrum are unstructured interviews such as life histories, whereby the main aim is to engage with the interviewee to make them feel comfortable to talk about the topic proposed to them (Brinkmann, 2014). Whilst being referred to as unstructured, there can never be an interview that is completely unstructured as the interviewee is guided by what the interviewer wants to learn, even if it is elicited through the asking of one question (Brinkmann, 2014). An element of structure is equally important to this study, as there are areas that the researcher wishes to investigate and therefore further questions will need to be asked.

#### **4.3.4 Semi structured interviews**

The third type of interview, semi structured interviews are regarded as the main method of qualitative interviewing (Packer, 2011). They require a more flexible approach, with open ended questions, allowing the researcher to steer the process to focus on areas of specific importance (Kelly, 2010). Flexibility also extends to the order in which the questions are asked, the way they are delivered and the length of answers received (Packer, 2011). Semi structured interviews aim to produce descriptive information from the interviewee, of their own experiences, perceptions and understanding (Brinkmann, 2014). The format is such that the interviewer can expand areas that they wish to explore further or that interest

them or they can equally close areas, (Josselson, 2013) whilst allowing the interviewee to contribute freely. The aspects of semi structured interviews as outlined here are applicable to the way in which data collection through interview is perceived for this study, in particular the opportunity to collate descriptive data pertaining to experiences, perceptions and understanding.

#### **4.3.5 Application of interview to this study**

From the above description, it can be said that for the purpose of this case study, semi structured interviews will be undertaken and will be informed by the data collated from the focus groups. The semi structured interviews will be held with the health professionals taking part in the guideline development group and will thus be a different population to those involved in the focus groups. Semi structured interviews will not only provide the opportunity to engage on a one to one basis, but will allow the researcher to explore concepts in greater detail guided by a structure, informed by the focus groups. The overarching objective of the interviews is to explore whether the PARIHS framework has cross cultural utility and an identification of the barrier and facilitators to knowledge implementation. As the interviews will be carried out with the same participants before and after completion of guideline development, it will also create an opportunity to understand the participants experience of the guideline development process, if it has an effect on their understanding of the development and use of guidelines, whether the guideline development process affects; a participant's knowledge, their views about evidence based healthcare and clinical guidelines.

Furthermore, the interviews will explore whether clinical guidelines such as these can be used in an international forum. They will also be an opportunity to consider the existence of any barriers or enablers that were experienced in the process of guideline development. To facilitate the evaluation of the PARIHS framework's cross cultural applicability to Malta, questions will be developed under the three overarching elements;

1. Context – enable the researcher to develop an understanding of the wider organisational context and culture of the country, whilst identifying facilitators and barriers within the context;
2. Evidence - consider broad aspects of the use of and concept of evidence, developed in a western context

3. Facilitation - explore the way in which evidence can be moved into practice including a consideration of the experience of developing guidelines through presentation of evidence and discussion in a committee structure.

#### **4.3.6 Practical considerations**

There are practical considerations that make undertaking semi structured interviews more successful and that will be applied to this case study. An interview guide or question prompts are often used to outline the areas to be explored. Neither are regimented, that is to say the questions may be asked out of sequence, as this is guided by the participant (Holloway and Wheeler, 2013). For this study, both an interview guide and question prompts will be used, as this will enable the interviewer to explore concepts further with the participant and for the participant to seek clarification about questions, concepts or language used (Holloway and Wheeler, 2013). Kelly (2010) acknowledges the importance of language and how it is used culturally for *“conveying meaning and context”* (Kelly, 2010)(P312) and thus acting as a window into the study population. This is a factor which is salient within this research study, bearing in mind the interviews are to be carried out in a cross cultural / bilingual context. To mitigate against misinterpretation and to ensure that the questions are asked in an accessible way to the participants (Roulston, 2010) it is intended that the focus group will provide an opportunity to understand cultural terms for concepts that are to be addressed in the interviews.

The focus group will also give an insight into non-verbal communication and gestures that are familiar to the culture and that convey meaning. This understanding can be furthered by the researcher talking to colleagues in Malta about differences and similarities in culture and reviewing literature around the subject. This information will enable interview questions to be written using local terminology which will be checked with local healthcare providers for accuracy. The importance of digitally recording the interviews is also relevant here, with the consent of the participants, as it will allow the interviewer to be more attentive to the interview as opposed to focusing attention on note taking (Kelly, 2010).

Semi-structured interviews have been used in Malta in a variety of settings. For example a study looking at the experiences of family caregivers of people with dementia (Innes et al., 2011) and a case study looking at the extent of how noticeable management involvement was in supporting interdisciplinary team working in an acute care setting, used semi-structured interviews to ascertain the experiences of patients, management and healthcare

professionals (Buttigieg et al., 2013). On this basis, the use of interviews in the cultural setting is regarded as an acceptable method.

On a practical level, interview questions need to be clear and ambiguity avoided (Holloway and Wheeler, 2013) and attention should be paid to the skills needed to facilitate the interview such as clear communication, empathy and active listening (Kelly, 2010, Josselson, 2013). Listening and questioning skills should not be underestimated as not only do they have an impact on what is recorded but they can also elicit more in depth responses. It is the intention of the researcher to use terminology that is used by the participants, making the interaction more relevant to them. There is no set directive over how long an interview should be, however consideration needs to be given to the participants such as whether they have busy working schedules, are elderly or are children (Holloway and Wheeler, 2013) and arrangements made to accommodate such factors. In this study, the researcher will need to be cognisant of the interviewees work commitments and ensure that all interviews are scheduled flexibly and at a time of convenience to the participant.

#### **4.3.7 Non face to face interviews**

Semi structured interviews can be facilitated through different mediums and are not only held face to face when both interviewer and interviewee are in the same place. Other mediums include telephone, Skype, email and internet chat, all of which have different limitations such as the latter being reliant on a level of communication skills that may not suit the ability of all (Brinkmann, 2014). The computer application known as Skype was developed in 2003, yet the practice of using it or other face time mechanisms as a means of carrying out interviews, is still relatively new, although they are becoming increasingly used (Weller, 2015) and is proving to be a methodology that is suited to qualitative interviewing (Deakin and Wakefield, 2014). In regards to Skype, its suitability has been acknowledged for a number of reasons both from a practical perspective and from that which benefits the participant. From a logistical perspective their use can reduce travel time, reduce costs, increase the reach of the research (e.g making it cross country or international), and afford greater flexibility regarding the time and place of interview (Deakin and Wakefield, 2014) (Sally, 2016). For the participant, they benefit from interviews being held in a place of their choosing and thus can be somewhere they are particularly comfortable in, the interview can feel less formal and therefore to some, less daunting (Sally, 2016, Weller, 2015), they can also result in greater responsiveness (Deakin and Wakefield, 2014). Yet whilst these

are aspects that have a positive impact, there are equally negative converse reasons as to why using Skype to interview is not necessarily suitable. Fore mostly, participants need to have the technology and be competent in using it. Following this, there is the potential for technical problems such as technical interference, 'lost' phone or internet connections (with resultant disruptions of flow of conversation) or the unsuitability of interview venue e.g. in a pub or other shared space. In addition there are the interpersonal factors such as not being able to fully see someone, difficulties of eye contact or observation of body language (Weller, 2015, Deakin and Wakefield, 2014, Sally, 2016).

A particular point to address is rapport and whether interviewing through Skype results in a greater or lesser amount of rapport between the interviewer and the participant. It has been suggested that rapport is lessened because of the reduced level of face to face interaction and ability to respond to body language and non-verbal cues (Sally, 2016). However, interviewing through such a medium has equally, been shown to facilitate communication and even allow participants to contribute more than if in a face to face interview (Weller, 2015). There are numerous factors that can affect the level of rapport either positively or negatively such as; prior communication between researcher and participant, familiarity with the research project and researcher, confidence in being interviewed in such a manner, the nature of the topic being discussed and the personality of the participant (Weller, 2015, Deakin and Wakefield, 2014). Weller (2015) concludes, in a study looking at internet based interviews as a viable alternative to face to face interviews, that they are viable; *"internet video calls can be technically challenging but if the audio and video quality are good and the researcher and participant are comfortable with the mode, then they offer a degree of flexibility and informality that physical co-present interviews can lack"* (Weller, 2015)(p44). In regards to this case study, it is intended that the interviews will be carried out on a face to face basis, but it is acknowledged that for logistical reasons, they may have to be facilitated by the use of telephone or Skype.

#### **4.3.8 Considerations when using semi structured interviews**

Semi structured interviews are an effective means of eliciting information and producing data, however there is concern that participants may respond to questions in a manner in which they think will please the interviewer (Holloway and Wheeler, 2013) or the responses given may not actually match the actions taken. Although it is challenging to ascertain the occurrence of either scenario, by being aware that it may occur, the

interviewer can structure questions to assist in eliciting real meaning. Interviewing can result in a plethora of data, indicating the importance of preparing well for interview to ensure it is manageable and that plenty of time is assigned to analysis (Brinkmann, 2014). As has already outlined, the researcher will ensure they are thoroughly prepared to undertake the interview in a timely manner through the use of an interview guide and prompts and an understanding of cultural factors that may place bearing on the situation. It needs to be decided prior to transcribing, how much importance is put on the inclusion of factors such as the correction of grammar and the inclusion of non-conversational elements such as laughter, hesitation and silence (Kelly, 2010). Researchers also need to be transparent about the role they have played in the interview (Brinkmann, 2014) and therefore, in this study this will be achieved through clear documentation of each interview, plus a recording of the interview. Critical reflection will be required from the researcher following each interview through the keeping of a reflective diary, which shall be kept by the researcher.

## **4.4 Observation**

As a method of data collection, observation has been used in qualitative research for a long time, most often in ethnography, yet is regarded as being applicable to other methodologies and has been considered by some as being underused (McNaughton Nicholls et al., 2014). It is regarded as a means of understanding a group of people as it affords the researcher the opportunity to record first-hand what they perceive of human interaction and behaviour, a particular setting and events in situ (Simons, 2014) (Yin, 2012). It is used as a stand-alone method of data collection but it is often seen as an adjunct to interviews (Holloway and Wheeler, 2013). It can be used to triangulate data, but it can also illustrate that there is dissonance between the two.

### **4.4.1 Types of observation**

Whilst observation is frequently used as an all-encompassing term, there are different types of observation in which the observer undertakes different roles. The choice of which form of observation is used is dependent on a number of factors such as epistemological perspective, the research question and the role in which the observer feels they can play. Gold (1958) defined four types of observation roles (Gold, 1958), categories which continue to be used today.

1. Complete participant – a covert role which can be controversial as the identify and actions of the observer are concealed (Holloway and Wheeler, 2013)
2. Participant as observer – the observer is known to the group and may develop a close relationship with the group.
3. Observer as participant (non-participant observation) – this is a more formal involvement for a limited amount of time. The observer is not as involved with actions.
4. Complete observer – no interaction between the observer and those being observed e.g observation takes place through a two way mirror (McNaughton Nicholls et al., 2014).

The third category, observer as participant is the form of observation that is most commonly used (Creswell, 2013), whereby the observer is known to the group and on a very limited basis interacts with them. It is this type of observation that is to be used in this case study, to observe a discussion regarding the implementation of the created guideline with the purpose being to see whether the understanding of evidence based practice is the same in the wider community and whether barriers and facilitators to implementation can be identified. Observations will also be made and recorded during the guideline development meetings, during which the evidence reviews will be discussed and recommendations made to create the clinical guideline. Participants will be informed that observations of the proceedings and discussions will be made. This is similar to a model of data collection used by Conklin et al (2015) who used non participant observations of guideline development meetings as an adjunct to interviews (Conklin et al., 2015). In a study protocol by Grove et al (2015), to look at barriers and facilitators to implementing elective orthopaedic surgery clinical guidelines, they similarly propose the use of observation, in a range of settings to establish an understanding of how the department either uses or prevents the use of clinical guidelines (Grove et al., 2015). A further study of relevance here, whereby non participant observation was used as well as interviews is by Nzinga (2009) who looked at barriers to guideline introduction and improvements in neonatal care in Kenya (Nzinga et al., 2009 ).

In regards to Gold's four types of observation there is a clear delineation between being an insider or an outsider to the group being observed (Allen, 2010). As an insider the observer becomes a part of the group they are observing, they may be absorbed into that group and develop an enhanced understanding and relationship with group participants, and as an outsider they are more detached from the group and thus see things from a more objective



position (Allen, 2010). The observer may be known to participants and this underpins the debate about the extent to which the presence of an observer has an effect on the actions of the participants, whether positively or negatively. In turn, this has been attributed to the underuse of observation as a method however conversely, it has been argued that it is exactly this that is, the presence of the researcher, what they observe, the effect it has on them, that adds to the richness of the data (McNaughton Nicholls et al., 2014).

A further influence on the role of the observer is that a person cannot divorce themselves from reality and the situational context as an observer comes to the situation with their own perspectives; personal, religious and cultural (Yin, 2012). The transparency of the observation process; the researchers role, why a particular observation focus was chosen, how events were interpreted, how they are influenced by the context they are in and how they influence the study all need to be recorded (Allen, 2010). Observation in this study will be used during the focus group and the guideline development group meetings. The form that it will take will be in keeping with Gold's (1958) identification of the observer being a participant as the researcher will be the facilitator in both circumstances (Gold, 1958). The focus of observation is to look at the importance of culture; personal, group, organisational, country, and the role it plays in the healthcare system and the effect it has on evidence based practice.

#### **4.4.2 Recording the observation**

The data which is recorded is also influenced by the observer as human nature dictates that they will be selective in what they record. As with the selection of the type of observation, Yin (2010) has identified three ways in which field notes can be recorded and a narrative written as; the researcher trying to recount from a perspective of neutrality, the researcher relaying the participants view or the researcher's interpretation of events (Yin, 2012). They are all acceptable methods of reporting observational data and their use is dependent on the aim of the data being collected. It is important to have a clear understanding of what will be observed to ensure that there is focus and the observer does not try to capture everything (McNaughton Nicholls et al., 2014). To assist in data collection, some suggest using an observational protocol to guide the data collection process to maintain focus and prevent the observer from being overwhelmed with information (Creswell, 2013). Clarity about the type of data being presented is paramount (Yin, 2009). As a continuation of this, selectivity of what is to be observed is also said to be dependent on the purpose and timing of the observation e.g. whether it is at the beginning of a study, is being used to develop a

general understanding or if it is further down the study programme and is for data collection or triangulation (McNaughton Nicholls et al., 2014).

The method of taking field notes also has an effect on the recorded observation. They need to be detailed and not over summarised to be a representation of the setting and what is seen and heard (McNaughton Nicholls et al., 2014). Notes are generally written, sometimes recorded and later transcribed and in some context they are filmed (Allen, 2010), although filming is not advised by some (Holloway and Wheeler, 2013). It is important to acknowledge the difficulty of writing all notes as the observation takes place and therefore if additional notes are to be written, they must be done immediately afterwards (Holloway and Wheeler, 2013). Reflexivity plays an important role in observation as it is advisable that the observer is self-reflective, but not too introspective, as a means of ascertaining why certain events have or have not been captured (Allen, 2010). In this study, the researcher will record the observations during the meetings and add any further observations immediately afterwards. It is important that reflexivity occurs in parallel (Allen, 2010) and therefore the researcher's self-reflections in this study will also include the reasoning behind observations.

#### **4.4.3 Practicalities of observation**

There are a number of practical considerations that need to be addressed when embarking on observation including identifying how access to participants will be achieved. This is most often done through a gatekeeper i.e. the person from whom permission is needed to conduct the observation and also whom may provide access to the people needed to be involved (Green and Thorogood, 2014). Informed consent needs to be granted from participants and from the place in which the observation is to take place (Holloway and Wheeler, 2013). The principles of data protection are the same as in all other research methods (and are outlined further in this chapter). If undertaking non participant observation, it has been suggested that the observer needs to be sensitive to the situation and maintain a low profile by placing themselves out of the way (Holloway and Wheeler, 2013) and making sure that they are introduced to the group by a group member (Creswell, 2013). Consent will be asked for in this study.

## 4.5 Being culturally aware

As culture is a key component of this study, it is appropriate for attention to be given to specific factors that are of particular relevance to carrying out research in another country and the challenges that this may bring. Specific aspects of culture that one needs to be considerate of have already been identified in the focus group and observation sections. The following however are areas of cultural awareness that should be addressed through all aspects of the study;

- a) Building up rapport and trust with the study participants; helping to inform participants' perceptions about the researcher and the overall process of data collection (Narag and R, 2014).
- b) Framing questions in a culturally sensitive manner (Liamputtong, 2008) and therefore developing an understanding of the cultural from which people in the study are from.
- c) Interpreting body language and spoken language; to reduce misunderstanding because of cultural differences, it is helpful to find out about any culturally specific traits or gestures, both spoken or non-spoken (Nilsen et al., 2013).
- d) Awareness of the perception of social interactions as these are reliant on how language is spoken (Temple and Young, 2004).
- e) Expectations of those being observed and how they are to be portrayed must be considered and listened to. For example there may be an expectation by participants that only positive data will be recorded (Narag and R, 2014) and thus any such misconceptions need to be explored.

As language is the essence of qualitative research, one cannot underestimate the importance of learning about and understanding the culture that is to be the context for a study, so that the researcher can undertake the study from an informed position (Hennink, 2013). It is important to remember the words of Geertz (1993) to appreciate the significance of any culture and why as researchers one needs to be aware of the impact of culture *"there is no such thing as a human nature independent of culture."* (Geertz, 1993)(p49). It is intended that the researcher is cognisant of this throughout the study.

## 4.6 Ethics

### 4.6.1 What are ethics?

The planning and development of research needs to be based around a central concept of ethics, the overriding aim of which is to keep participants safe and cause them no harm (Simons, 2014). Ethics has been described as *“the process of studying moral standards and examining how we should interpret and apply them in various situations”* (Cunningham et al., 2013) (p26). Whilst social science has been involved in the development of ethics since the 1960's, its centrality in qualitative research has come more to the fore in recent years, largely due to the impact of regulation.

Ethical regulation, in a formalised manner has been in force since the Nuremberg Code of 1947, which in its original form mainly covered ethical principles relating to medical experiments, but was later widened to include psychology (Traianou, 2014). Since then, numerous guidelines and frameworks worldwide, from various institutions and organisations, all of which have similar core principles have been developed (Webster et al., 2014). In recent years, the regulatory aspects of ethics in healthcare in the UK has been shaped by the 2005 Department of Health Research Governance Framework for Health and Social Care, all hospitals in the UK have ethics committees, universities are covered by ethics frameworks and professional organisations have ethical codes of research (Urquhart, 2012 #36) (Holloway and Wheeler, 2013).

Debate however exists over the suitability of ethical regulations to qualitative research, as they are based on a biomedical model (Holloway and Wheeler, 2013). An unfortunate consequence of this model is that the impact on qualitative research can be quite negative as the regulations do not necessarily fit with qualitative methods of inquiry i.e. its flexibility in research design and the data collection which happens in environments that are not often in the control of the researcher (Traianou, 2014). In addition, ethics guidelines are sometimes regarded as being inflexible, restricting researchers from being responsive to circumstances which is particularly problematic in qualitative research where the study often evolves over time, resulting in unanticipated dilemmas (Webster et al., 2014). There are clear core principles of ethics which are discussed below yet this does not guarantee that understanding and applying ethics to a research process is straightforward.

#### **4.6.2 Main principles of ethics**

There are three overriding principles of ethics that are often cited as being the cornerstones of ethical behaviour in research; the minimisation of harm, (Holloway and Wheeler, 2013); informed consent (Goodwin 2006); confidentiality and anonymity (Webster et al., 2014). These concepts are further explored below.

##### **4.6.2.1 Minimisation of harm**

As noted, the basic tenet of research ethics is that the research should not cause harm to any participant and all harm should be minimised (non-maleficence) (Cunningham et al., 2013). When referring to harm it predominately applies to both physical and psychological harm, and in many ways it is minimised through the other two principles of ethics.

However, harm does not just relate to personal harm in a physical or psychological sense, but extends to other aspects of harm such as; reputational harm to a participant or other they have a personal relationship with; hardship caused such as loss of employment; the negative impact caused to the study or the researchers' organisation or company (Traianou, 2014).

A further aspect of harm, is potential harm that may be caused to the researcher as a result of carrying out the study, and thus which they and their organisation need to be aware of (Webster et al., 2014). Mitigation against such potential harm to the researcher can be achieved through an awareness of factors such as; the place where the research is to be conducted e.g. is it safe for the researcher and whether the researcher has the skills to address possibly sensitive topics of discussion ensuring that professional boundaries are maintained (Holloway and Wheeler, 2013). There is clearly a need to protect the researcher by providing support and training where difficult topics are to be addressed to minimise personal harm. One also needs to keep in mind the interests of the profession and the institution for whom the research is being carried out and ensure that no harm befalls them (Holloway and Wheeler, 2013).

Even with all factors taken into account it can be very difficult to avoid all harm, as some studies carry greater risk than others, for examples those in which the data to be collected is of a more sensitive nature or whereby participants are more vulnerable (Traianou, 2014). This is an indication as to why a clear assessment of harm is needed for all parties involved in a research study, so that appropriate steps are taken for it to be minimised. Such an

assessment will be carried out and all efforts will be made to ensure that no harm is caused to any participant or institution in this study.

#### **4.6.2.2 Informed consent**

Informed consent must underpin participation (Webster et al., 2014) for research to be ethical. Informed consent is the process whereby participants are provided with enough information about the study to allow them to make an informed decision as to whether they wish to participate (Fisher and Aushlio, 2008). Information is provided to the participant following which they decide if they wish to be a participant in the study. The process of informing the participant about the study must also be free from either deception by omission (withholding important facts from participants) or deception by commission (purposely lying to or misleading the participant), to allow them to make a decision (Cunningham et al., 2013). Following the provision of information, no form of coercion by either the researcher or any other person should take place as it is paramount that participation should be undertaken as an expression of free will (Holloway and Wheeler, 2013) (Stark and Hedgecoe, 2010).

As an illustration of a person's acceptance to participate a consent form is usually signed. Whether a signature is needed is debatable as some state that agreement to consent does not always have to be written as long as there is verbal agreement which is recorded by the researcher (Stark and Hedgecoe, 2010, Traianou, 2014). Others regard signing the consent form as a positive, stating that it creates a contract compelling people to participate and making it less likely for them to withdraw (Webster et al., 2014). Yet, the expectation that someone will sign a form needs to be carefully considered as there are a number of reasons why this may not be appropriate; there may be a cultural reason not to sign, one cannot assume that all participants are literate, refusal to sign may be a way of asserting oneself, as well as not really understanding the reason or need to sign (Stark and Hedgecoe, 2010, Traianou, 2014).

In order for the study information, which underpins the process of informed consent, to be delivered appropriately a system for providing information and receiving consent in return needs to be in place (Holloway and Wheeler, 2013). The following are the main key points that need to be disclosed to participants as part of informed consent;

a) The purpose of the research, its aims, who is funding it, who is conducting the study, how and who to contact if the participant has any questions,

- b) Participation is voluntary and participants have a right to leave at any time during the study without giving a reason,
- c) What is expected of participants and whether there are any risks involved in taking part,
- d) Confidentiality, anonymity, data storage.

(Webster et al., 2014, Holloway and Wheeler, 2013, Stark and Hedgecoe, 2010).

This information is usually presented in a letter, to be read by participants but that can be read to them if necessary. Once the information has been relayed, an opportunity should be given for the participant to ask questions and for more information to be provided whether it be verbal or written. One may not automatically assume that the provision of information occurs just once as sometimes information needs to be given on more than one occasion, such as at different stages of a research project, to ensure that participants' understanding of participation is maintained (Webster et al., 2014). The concept of when to provide such information is one that is debated as some say that the timing of the data provision can bias the study, for example with information for a focus group, it may be seen as directing the course of conversation (Stark and Hedgecoe, 2010).

In addition to the gaining of consent, thought and planning needs to be given to the possibility that someone may withdraw consent after data has been collected. If this was to occur then the data would need to be removed unless permission was given by the participant to retain any data given up to that point in time.

The above concepts will be used to shape the informed consent to be given to participants of this study, ensuring openness and transparency. Written consent will be requested for; participation in the focus groups, at more than one time point for each set of interviews (pre and post) and observation during the guideline development group.

#### **4.6.2.3 Confidentiality and anonymity**

Confidentiality and anonymity are two concepts that are central in maintaining ethical standards in all types of research. However, it is important to be clear about what each entails and to what level they can be maintained during research. Although confidentiality and anonymity are concepts that are associated with each other, they are not interchangeable. Confidential pertains to the notion that information is "*intended to be kept secret*" (Oxford Dictionary, 2017) and that which is disclosed is not to be repeated,

unless with the permission of the participant (Wiles et al., 2008). Anonymity originates from the Greek work “anōnumos” meaning ‘*nameless*’ (Oxford Dictionary, 2017 ) and means just that, ‘not known’, which in the context of research, this means the identity of the participant remains unknown.

#### **i) Confidentiality**

Maintaining full confidentiality can be challenging, for example when using direct quotations in the documentation of findings (Traianou, 2014) (Wiles et al., 2008) and therefore some argue that full confidentiality can never be promised as it is unattainable (Holloway and Wheeler, 2013). However, there are various steps that can be taken to maintain confidentiality such as respecting the wishes of the participant, for example they may agree to being recorded but may request not to be quoted in text (Webster et al., 2014) and explaining exactly what will be reported and how. In addition, if data collection is taking place in a group context such as a focus group or observation then it needs to be made clear that participants must respect the confidentiality of each other (Webster et al., 2014, Traianou, 2014). Furthermore, all those who handle research data must maintain confidentiality (Wiles et al., 2008).

Although these practices can be put into place to uphold confidentiality, there are situations in which data does need to be disclosed, such as if the participant divulges that they are in danger or have committed a crime (Stark and Hedgecoe, 2010). Confidentiality also relates to how participants are accessed as it is often achieved through a third party or gatekeeper e.g through a lead consultant in a hospital (Webster et al., 2014). Therefore, maintaining confidentiality in such circumstances must be considered as the gatekeeper is in a position whereby they can identify who is participating (Traianou, 2014).

Confidentiality is not just about the way in which data is reported but also the way in which it is handled and stored. This is largely covered by legal and regulatory standards, in particular the Data Protection Act in the UK (1998) which addresses principles on handling and storage of data, the use of data, the transference of data and length of time for which data should be kept. Areas that are particularly relevant to research data are factors such as the importance of storing personal information that can be used to identify a person separately to recorded data (Wiles et al., 2008), storing data files in locked cabinets or if electronic ensuring files are encrypted / password protected and making sure when sharing data electronically appropriate precautions are taken such as using shared folders and not



emailing documents (Webster et al., 2014). In addition to the Data Protection Act (1998), organisations such as universities have their own regulations on how long information should be kept for and therefore it is important to adhere to the regulations of the organisation in which one works.

## **ii) Anonymity**

Anonymity can be operationalized by ensuring that all identifiable characteristics are removed from the reporting of a study, information that does not impact on the study can be altered such as inventing a place name where the study took place and of course making the individual anonymous (Holloway and Galvin, 2017, Wiles et al., 2008). If any of these actions are taken then it must be documented and not altered to a point that accuracy of reporting is questioned (Traianou, 2014).

All aspects of confidentiality and anonymity as outlined here will be respected within this study. Maintaining anonymity will be of particular importance as the population of Malta is small and healthcare professionals of medical specialties are easily identifiable. Thus reporting will need to ensure that individuals can not be identified by not discussing individual healthcare professions.

### **4.6.2.4 Respecting ethics**

Adherence to research ethics applies no matter where the research is being carried out and should not differ when working in a cross cultural environment. Whilst the ethics do not change, there may be a need for awareness of additional factors, as the concept of ethics in research and explaining its processes and principles is not necessarily a concept that has cross cultural applicability (Stark and Hedgecoe, 2010). Examples of where greater consideration may be needed are in situations where; the concept of ethics does not exist; an assumption of the applicability of specific components of research ethics such as autonomy cannot be made; it may not be usual for the individual to decide to participate or to provide consent as this may reside with another within the culture e.g. the head of a family, tribe or organisation (Traianou, 2014). Difficulties may then follow for example deciding the extent to which one should insist on gaining individual consent (Traianou, 2014) at a risk of undermining the cultural views of the population one wishes to engage with. When considering ethics in a cross cultural environment, the aspects of cultural sensitivity that have been previously outlined also apply, particularly a knowledge and understanding of the culture within which one wishes to work.

In application to this study it is imperative that all the ethical principles as outlined above are adhered to and that cultural norms are respected.

## **4.7 Analysis.**

### **4.7.1 Introduction**

There are a variety of methods of analysis that are applied to qualitative data, which should be applied with rigour, scrutiny and integrity, factors that are important in making the basis of solid analysis (Green and Thorogood, 2014). Choosing which type of qualitative analysis is informed by factors such as; the type of data collated (Spencer et al., 2014), the aims of the study, the research questions, research paradigm and its intended outcomes, such as whether it is used as a function to describe or whether explanations can be deduced from the description or whether a theory can be derived (Green and Thorogood, 2014) (Spencer et al., 2014, Gale et al., 2013). A thorough qualitative analysis should result in the illustration of the depth of the subject being researched (Green and Thorogood, 2014).

Analysis is by nature an iterative process that often requires theories and thoughts to be re-interrogated, interpreted and continuously developed (Ormston et al., 2014) and thus is a process that should start at the beginning of qualitative data collection. These considerations and those that follow are applied to the decision making used to identify the most appropriate form of analysis for this study.

There are two overarching approaches to qualitative analysis; substantive and structural (or constructionist) (Spencer et al., 2014). The substantive approach concentrates on what the text is *saying* and is therefore relevant to analysis such as thematic analysis, grounded theory, content analysis and framework analysis. On the other hand, the structural approach centres on what the text is *doing* as opposed to what it is saying, i.e. how the language is structured, which is thus suited to narrative and discourse analysis (Spencer et al., 2014, Gale et al., 2013). At this point it can be said that a substantive approach will be taken in this study.

The epistemological approach one takes also has an influence on the method of qualitative analysis identified, i.e. whether it is inductive and thus looking for the patterns that emerge from observations made or deductive whereby theory and ideas result from the process of research and analysis (Ormston et al., 2014). Qualitative research is generally regarded as being inductive (Strauss and Corbin, 1998) however both induction and deduction often

occur at different stages of the research process (Ormston et al., 2014). On the basis of this understanding for this study, a predominately inductive approach shall be used.

#### **4.7.2 Data to be analysed in this study**

The focus groups are to be analysed to ascertain the views and understanding of the participants in regards to evidence based practice and what it means to them. In addressing these areas, further insight into the three overarching elements of the PARIHS framework; evidence, context and facilitation will also be explored. In the semi structured interviews the data will be analysed to establish the applicability of the PARIHS framework cross culturally. Therefore, to enable the identification of an appropriate analysis for this study, consideration will be given to two substantive approaches; thematic analysis, and framework analysis as the analysis of the data collected in this study is concentrating on the meaning of the data. As a result this section will review these two approaches and provide an in depth overview of the chosen method of analysis.

#### **4.7.3 Thematic analysis**

Thematic analysis is a method of qualitative analysis that looks at the content of the data in order to identify the themes and patterns in it (Spencer et al., 2014) and to compare these themes from one set of data to another and identify patterns (Green and Thorogood, 2014). Whilst themes and patterns are identified from the data, themes are not always those that emerge from the data, as some may be pre assumed, identified from existing literature or based on professional experience and used as part of the process of data collection (Ayres, 2008). In keeping with other qualitative methods of data analysis, the process of thematic analysis is not sequential and individual 'steps' of analysis; coding, data management, identification of themes and patterns, may be revisited (Ayres, 2008). As a method of analysis it has wide accessibility as it is not connected to a particular theoretical construct (Spencer et al., 2014). Thematic analysis can be used as a stand-alone method of analysis yet it is also a component of other analyses such as grounded theory (Spencer et al., 2014) and framework analysis. It is commonly used in health research as it is applicable to research that intends to provide answers to specific issues or find common responses (Green and Thorogood, 2014). However, it is limited if one wishes to transcend the themes on the surface or aims to identify theories that may evolve from the data, which is the intention of this study. Therefore, thematic analysis will not be employed in this study,

however it is important to acknowledge that it is the basis of framework analysis, which allows for the deeper analysis of data.

#### **4.7.4 Framework analysis**

Framework analysis was developed by the National Centre for Social Research (NCSR) in the 1980's, since when it has continued to evolve (Spencer et al., 2014). The NCSR have a remit for the development of social and public policy and therefore framework analysis was originally developed with a focus on the production of robust policy (Green and Thorogood, 2014).

As a means of qualitative analysis it is clearly structured with defined steps that act as a guide through the process. These steps, like other analytic procedures run either as a continuum or they can be operated in parallel and can be repeated during the analytical process (Ritchie and Spencer, 1994). The orientation of the approach is reflected in the name 'framework', as the essence of the process is the organisation of themes from the data into a written framework, i.e. a matrix (or matrices) populated with participant data (Ritchie and Spencer, 1994) and themes from the literature. The matrices work to maintain data integrity of individual respondents as the data is continuously linked to its original source (Green and Thorogood, 2014) (Gale et al., 2013). By structuring the data in this fashion, comparisons within and across data are more easily facilitated (Gale et al., 2013) (Ritchie and Spencer, 1994).

Framework analysis is independent of any epistemological or theoretical links and can be used with either inductive or deductive coding (Ritchie and Spencer, 1994) (Gale et al., 2013), both of which are factors that increase its flexibility and application (Gale et al., 2013). Framework analysis has been identified as being suitable for case studies (Ritchie and Spencer, 2000) and semi structured interviews (Gale et al., 2013), is clearly structured, and allows for comparison across themes (Gale et al., 2013). Themes may be those which emerge directly from the data (inductive) or those that are applied to the data from existing literature or theories (deductive). Furthermore, framework analysis is a clear, step by step process of data analysis which has been applied to a variety of topics in an extensive international arena.

On the basis of these factors, its working application and its suitability to case study, framework analysis has been identified as the method of analysis best suited to this study.

The following outlines the process of framework analysis indicating how it is applied to analysing data.

#### **4.7.4.1 Framework analysis in practice**

There are a number of studies in adjacent areas to this thesis which have successfully used framework analysis. In a study looking at the influences on and the process of decision making of guideline development groups, (Gardner et al., 2009) used a mixture of data analysis methods including framework analysis. Framework analysis was applied to the analysis of data from verbatim meeting transcripts and semi-structured interview transcripts (Gardner et al., 2009). In another study looking at experiences and views of general practitioners (Tonkin-Crine et al., 2011) looked at antibiotic prescribing practices in five European countries. They used framework analysis to analyse semi-structured interview which were held to explore the experiences and views of general practitioners usage of antibiotics. In South Africa, (Marais and Petersen, 2015) looked at factors within the healthcare system regarded as blocking or facilitating the implementation of a model of integrated mental healthcare through a series of semi structured interviews. Framework analysis was identified as suitable because the study outcomes were directed at improving policy and legislation, which is what framework analysis is not only often used for but was developed to do. Additionally, it highlighted the barriers and facilitator to the implementation of the mental health policy. As a final example, in Iran Imani-Nasab et al (2014) used framework analysis to evaluate a series of semi-structured interviews held with those involved in the development of evidence based health policy documentation (Imani-Nasab et al., 2014). In this example through the use of framework analysis, 3 main areas; behavioural, normative, control beliefs were identified as barriers and facilitators to development.

The reasons outlined above underpin why framework analysis will be used to analyse the case study data; focus groups, semi-structured interviews and observation data. As framework analysis will be used a further explanation of its processes is given below.

#### **4.7.4.2 Five steps of framework analysis**

Whilst like other types of data analysis, framework analysis has evolved since it was initially developed, it still maintains its form as a five step approach to data analyses; familiarisation, identification of a thematic framework, indexing, charting, mapping and

interpretation (Ritchie and Spencer, 1994). Each stage is important and will be briefly defined to provide an understanding of the process that not only underpins the theory of framework analysis but to clearly define how this analysis will be used in relation to this study.

**Familiarisation** is the first stage of the process and is regarded as forming the basis of the whole analysis. The emphasis of this stage is the importance of getting to know the data well, resulting in an in-depth understanding and overview of all the data (Ritchie and Spencer, 1994). To achieve this, the researcher must re-visit and re-read notes, re-listen to recordings and transcripts until the point at which they are sufficiently immersed in the data (Gale et al., 2013). In cases in which there is a particularly large amount of data, then careful selection of what one needs to be familiar with must become the focus (Spencer et al., 2014 -a). During this process of familiarisation the aim is to identify and record relevant ideas, observations, interesting and recurrent ideas in the data as well as recorded any observations about the interview situation as a whole (Spencer et al., 2014 -a). These notations form the basis of the **thematic framework** (Ritchie and Spencer, 2000). In this study, familiarisation will focus on the transcripts from the focus groups, transcripts from semi-structured interviews and observations made and recorded.

The notes created during data familiarisation, often result in an all-encompassing list of relevant items, however for the thematic framework to take shape, this is reduced (Spencer et al., 2014 -a). During this process, it is imperative that the researcher continually cross checks this emergent list to the original aims of the research and previously identified factors (Ritchie and Spencer, 2000). From this list, an initial thematic framework is developed with the data grouped into themes and subthemes and an explanation of the subthemes recorded to ensuring there is clarity about how they are used and their meaning (Spencer et al., 2014 -a). As qualitative analysis is a dynamic process the thematic framework may often change over the course of the analysis as it is revised and new themes developed (Gale et al., 2013). By recording the data under themes, the researcher then has an ability to sort and compare the data (Spencer et al., 2014 -a). The process is very reliant on analytical thinking and application of the original question.

Once the framework has been constructed the data is ready to be annotated according to the themes and subthemes, this is referred to as **indexing** (Spencer et al., 2014 -a). It is important to note that a section of data can have multiple themes and subthemes applied to it (Spencer et al., 2014 -a). During this process the researcher continuously develops

views about the data (Ritchie and Spencer, 2000). The process itself calls for strict documentation particularly as references are indexed, linking them back to the main text, thus increasing its accessibility to others who may wish to ascertain how, or on what, conclusions were based or decided upon (Gale et al., 2013). When all the data has been indexed, it is **sorted** so that similar data is grouped together. The overall role of sorting the data is that it enables the researcher to give attention to the details and differences of each topic, although data may be sorted into more than one location (Spencer et al., 2014 -a).

Following this, **charting** takes place, whereby charts are created by pulling out the data under themes. The charts act as data summaries and by collating under themes it allows for comparisons to be made both within and between individual interviews (Green and Thorogood, 2014). During this process the text is continuously linked to the source data, again increasing the robustness of the data trail (Ritchie and Spencer, 1994). The final step of the analysis journey is referred to as **mapping and interpretation**. By this point, all data has been arranged under themes and subthemes and the process of looking for patterns, explanations and relationships between themes and interpretation of the full data set begins (Green and Thorogood, 2014, Gale et al., 2013). The process of framework analysis as defined here will be applied to this study.

#### **4.8 Summary of methods and methodology considerations**

To recap, the study will be carried out using a constructivist paradigm, the notion that humans are actively involved in constructing knowledge (Ormston et al., 2014). This paradigm is based on a interpretivist epistemology and a relativist ontology (Denzin and Lincoln, 1998). A case study methodology will be used as it is compatible with the constructivist paradigm (Spencer et al., 2014) and by using a variety of methods an in depth understanding of the data can be obtained as well as triangulation of data (Roulston, 2010). The methods to be used are focus group, semi-structured interviews and informal observation. Framework analysis will be used to analyse the data from this study as it can be used both inductively and deductively and has been identified as being suitable for case studies (Ritchie and Spencer, 2000).

## 5 Chapter five - Carrying out the case study

### 5.1 Overview

Here follows an account of the case study and how data was collated. All aspects of data collection are outlined to capture how they took place and any difficulties encountered. Prior to the case study being undertaken, as outlined in chapter one the researcher made sure they learnt not only about the country but how healthcare was delivered in country. This was undertaken not only to be respectful to the participants by illustrating some knowledge, but to help facilitate the researcher's understanding of responses to questions and conversations.

This study was undertaken in two localities. It was originally planned to be carried out in the Hashemite Kingdom of Jordan, through the Jordanian Royal Medical Services. After the first stage of the study (a focus group) had been achieved, unfortunately the study had to be stopped as outlined in chapter 2, section 2.8.2. The data collection therefore had to be paused until a new study site could be secured. A large hospital in Malta was identified and the study was started again from the beginning. As the study re-commenced from the beginning in Malta, it is still regarded as a single case, case study, although findings from the Jordanian site are reported. The following diagram (Figure 2) is an illustration of the order in which the case study components were carried out:

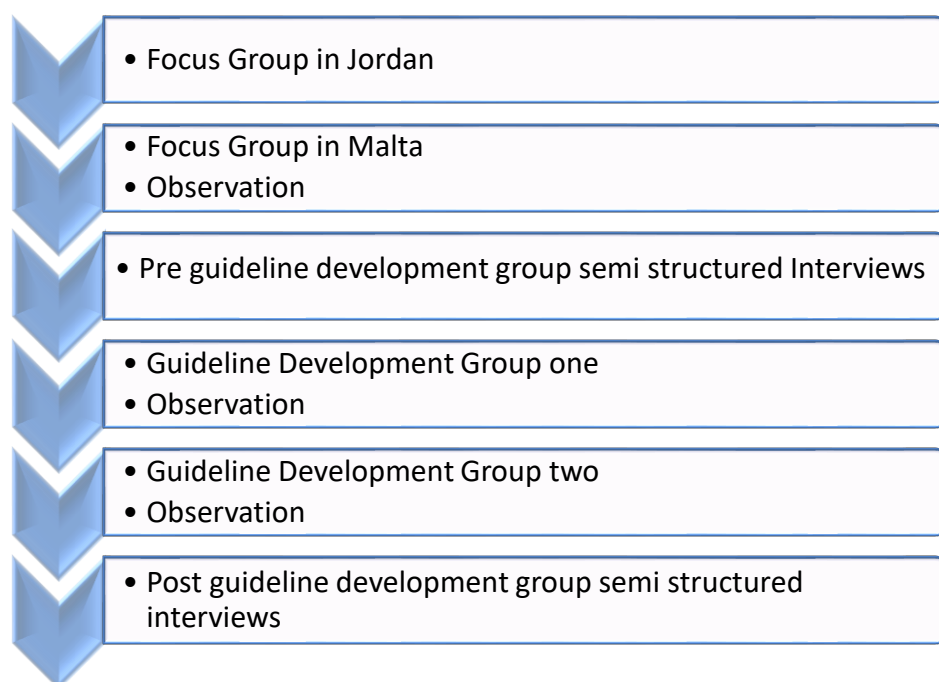


Figure 2: Order of case study



## **5.2 Obtaining ethical approval and access to participants**

The proposal submitted to both Warwick University and the Jordanian Royal Medical Services in the first instance, was written in an explanatory manner, allowing for easy accessibility and understanding for all. The subsequent proposal submitted to the University of Malta was written in the same manner.

### **5.2.1 Warwick University**

Ethical approval was applied for from the University of Warwick Biomedical and Scientific Research Ethics Committee (BSREC). Ethical approval was granted with no amendments. (Appendix A).

Following the decision to transfer the study to Malta, a substantial amendment request was made to the University of Warwick Biomedical and Scientific Research Ethics Committee (BSREC). Ethical approval was granted with no amendments. (Appendix B)

### **5.2.2 Jordan**

#### **Jordanian Royal Medical Services**

Ethical approval was sought from the Professional Training Division of the Jordanian Royal Medical Services to hold a focus group with attendees at the 7<sup>th</sup> International Conference of the Royal Medical Services, Jordan November 2014. The focus group was given ethical approval without any amendments needed. (Appendix C).

Permission was given to access participants directly at the 7<sup>th</sup> International Conference of the Royal Medical Services, Jordan November 2014, to invite them to attend the focus group. The invitation to attend the focus group was sent to the RMS ahead of the conference with a request for it to be dispersed where possible.

### **5.2.3 Malta**

#### **University of Malta**

Ethical approval was applied for from the University of Malta Research Ethics Committee. Application was made to the university as the research was to be carried out under the supervision of the Head of Department who is a member of the Faculty of Medicine and Surgery. Following application the researcher was invited to attend the Faculty Ethics

Committee meeting on the 6<sup>th</sup> November 2015 to enable for any clarification of the research to be sought and understood. Following the meeting, the researcher was requested to add their supervisor's name on the second page of the proposal, add details regarding recruitment and ensure the consent forms and letters were signed by the researcher and their supervisors. The researcher was subsequently requested to amend the consent form to only have an option to 'opt in'. All amendments were made and full ethics approval was granted. (Appendix D).

Access to participants in Malta was obtained through the Head of the hospital department in the first instance. Once he had been in contact and ascertained who would participate in the focus group, semi structured interviews and guideline development, the researcher made contact with potential participants.

### 5.3 Sampling

The essence of qualitative research is to gain personal accounts from people about the research topic (Taylor, 2013) and not to seek statistical representation (Britten, 2006). In qualitative research, an increase in the sample size does not guarantee new evidence will be found once saturation is reached. Saturation is defined as the point in data collection at which new data does not generate any new ideas or understanding relating to the research question (Pawluch and Neiterman, 2010, Ritchie et al., 2014a).

To meet the requirements of this study, whereby data was to be gathered from a cross section of healthcare professionals), two types of sampling were identified; convenience sampling (which was applied in Jordan) and purposive sampling (which was applied in Malta).

Convenience sampling is that which is based on participant availability as the participants are regarded as being 'convenient' to access and likely to respond and is not intended to create a random group (Cunningham et al., 2013, Bowling, 2014). Due to the context in which the focus group was to be carried out in Jordan, convenience sampling was identified as being a suitable process for recruiting participants. It was identified with the need for practicality and realism in mind as it was not possible to send out invite letters prior to the conference, and therefore participants were to be identified at the conference.

Purposive sampling is deliberately non- random as *"respondents are selected because they have knowledge that is valuable to the research process"* (Bowling, 2014)(p210). It is the

process of identifying participants based on what the study wishes to explore for example the delivery of care or policy (Ritchie et al., 2014a) and how the participants can inform this (Barbour, 2010). By sampling in this way, one can make sure that all aspects of the study are covered such as the need for multidisciplinary representation whilst ensuring there is diversity (Ritchie et al., 2014a). In Malta, all participants for the focus group, semi-structured interviews and the guideline development group were selected using purposive sampling as there was the requirement for a cross section of healthcare professionals.

## **5.4 Study sites**

A description of the sites where the case study was carried out is outlined here.

### **Jordan: The 7<sup>th</sup> International Conference of the Royal Medical Services, Dead Sea,**

The 7<sup>th</sup> International Conference of the Royal Medical Services, was held between the 4<sup>th</sup> and 7<sup>th</sup> November 2014 at the King Hussein Bin Talal Convention Centre, Dead Sea, Jordan. Arrangements were made with conference organisers to hold the focus group during the conference, at the convention centre.

### **Malta: A large hospital in Malta**

Arrangements were made for access to a private meeting room in the hospital department for the focus group, interviews and the guideline development. Interviews were also held in offices of participants, in public spaces within the hospital or on the phone.

## **5.5 Focus group Jordan**

### **5.5.1 Focus group questions**

Focus group was chosen as a method of data collection as it was identified as being a suitable method through which an understanding of the case could be established. Additionally it was regarded as being an initial point of exposure to the Jordanian healthcare workforce, an opportunity to hear and record how evidence based healthcare is practiced in Jordan, whilst being an opportunity to explore the three overarching elements of the PARIHS framework; evidence, context and facilitation. Questions for the focus group were therefore developed to explore the following;

- a) what evidence means to the participants,

- b) what underpins their healthcare practice and
- c) how evidence was perceived / knowledge being used in healthcare settings in Jordan.

To make certain the questions were clearly written, the researcher read them to colleagues and any changes were made following feedback. The researcher also rehearsed them to allow for clear delivery of the questions and practice in the use of prompts. The full table of questions can be seen in Appendix E.

### **5.5.2 Pre-organisation of the focus group**

In parallel to defining the questions to be asked, preparation for the focus group was made. All preparation was carried out in collaboration with the link person at the RMS and the conference organisers, with both parties being extremely supportive and helpful in ensuring the focus group took place. Requirements for the focus group were explained through email i.e. the length of the session and the need for a private room. To help facilitate this, it was agreed that the focus group be acknowledged as a lunch time session (to prevent it clashing with other conference sessions) in the conference programme for which attendance was by private invitation only.

The RMS was informed that invitation letters (Appendix F), would need to be distributed to doctors, nurses and allied health professionals. They agreed that this was acceptable and so an invitation letter, which explained; the intention of the focus group, what participation would involve, that the session would be recorded and all data would be confidential, was sent in advance to the conference organisers and the researcher's link person at the RMS for approval and distribution prior to the conference. Distribution was meant to be a random selection of healthcare professionals. The RMS agreed to send out as many as they could to ensure a good sample. The researcher was prepared to hold two focus groups if needed. In addition, a brief research project information letter and approval request (Appendix G) was sent to provide the conference organisers with an understanding of the overall research project.

### **5.5.3 Adaptation to the organisation of the focus group**

Adaptation needed to be made to the organisation of the focus group on arrival to Jordan and the sample type was changed to a convenience sample. This was achieved by the researcher, accompanied by a member of the RMS, randomly and directly approaching a mix of Jordanian healthcare professionals at the conference to invite them to the focus

group. All healthcare professionals that were approached were given an invite to the focus group.

#### **5.5.4 Data capture**

To ensure all interactions were fully captured, the focus group was digitally recorded. All participants were made aware of this in both the invitation letter and the consent form (Appendix H). The consent form also gave participants the option to stipulate they did not wish for their contribution to be recorded. The researcher explained at the beginning of the focus group that the session was to be digitally recorded and notes taken by herself and an assistant but that all data was confidential.

The group was facilitated by the researcher, with an assistant present to make notes of the session. To assist in data capture, a plan of where all participants were sitting was made and all participants provided their names and profession at the beginning of the recording. This information was used to aid transcription.

#### **5.5.5 Participants**

Approximately 30 healthcare professionals were invited to the focus group. Eleven attended in total.

#### **5.5.6 The focus group set up**

Prior to the focus group taking place, the researcher and assistant made sure that they were appropriately prepared to enable the focus group to run smoothly. The researcher briefed the assistant on the aims of the overall research, the function of the focus group and the questions that were to be discussed. Particular items were highlighted as needing the attention of the assistant were; recording the seating plan of participants, making notes where possible, ensuring the collation of consent forms. The researcher was clear about all questions, and had adequate and appropriate prompts. The digital recorder was checked prior to the session, and just as the session began, to make sure it could pick up all who spoke.

The room in which the focus group was to take place was large and it was not possible to keep the room private. Therefore, a circle of chairs was set up in a corner of the room, far from the door, to create as much privacy as possible and to ensure that all could be heard.

### **5.5.7 The focus group introduction**

Each participant was provided with an information sheet and a consent form as they joined the group. As the information sheet and consent form were in English, the researcher ensured there was sufficient time to read, compute the information and ask questions. To ensure understanding, as an introduction to the session the main points outlined in the consent form, in particular the importance of keeping anonymity and confidentiality and signing them, were carefully reiterated. Particular emphasis was put on the session being recorded and the option to request to be deleted from the recording. This however was not necessary as all participants fully consented to the focus group and signed the forms. They were collected from the participants at the beginning of the session.

### **5.5.8 The focus group in action**

All participants introduced themselves to the group stating their name and healthcare profession. It was a diverse group in regards to a mix of healthcare professions, gender and army rank. Whilst this was regarded positively, the researcher was concerned it may cause barriers to participants speaking in front of each other. These concerns however were proven to be unsubstantiated as all participated in the focus group as much as they desired. Aware of the fact that all conversation and questions were in English, attention was given to inviting all to contribute when a question was asked and engaging with all when something was clarified. For those who were less forthcoming than others, their opinion was asked by the researcher, ensuring eye contact was made and enough time given to respond or seek clarification.

The questions were asked in the order in which they were set, however when a question had been addressed through prior conversation, it was not repeated. This required reactivity to the conversation and an ability to conduct the conversation in the direction of the questions, so that as much information as possible could be captured. Conversation was fluid and participants were respectful of each other whilst also assisting each other when occasional difficulties arose in expressing themselves in English. The assistant took notes throughout and created a seating map so that contributors could be identified when transcribing. The researcher also took notes as prompts for later use.

Due to the time constraint of holding the focus group during a lunch break, the focus group lasted for 40 minutes. Although group conversation was still following at this point as they were very responsive and eager to talk, all questions had been covered in detail.

The researcher thanked the participants for their time, their contribution and ability to be flexible to their surroundings. The participants expressed that they had enjoyed the experience and were keen to offer any other help if needed.

## **5.6 Focus Group Malta**

### **5.6.1 Focus group questions**

The questions used in Malta were the same as the ones used in Jordan. Although the study was started again from the beginning, it was decided that it would be beneficial not to make any changes to allow comparisons to be made. As with the Jordanian focus group, it was regarded as being an initial point of exposure to the Maltese healthcare workforce, an opportunity to hear and record how evidence based healthcare is practiced in Malta, whilst being an opportunity to explore the three overarching elements of the PARIHS framework; evidence, context and facilitation. Data from the focus group was also used to inform the semi-structured interview questions.

The full table of questions can be seen in Appendix I.

### **5.6.2 Pre-organisation of the focus group**

Preparation for the focus group was carried out in collaboration with the head of the department with whom the researcher was liaising. The head of department and his administration team were extremely supportive and helpful in ensuring the focus group took place. As the researcher had no contact with healthcare professionals in Malta, responsibility was passed to the head of department to invite people to attend the focus group as part of a purposive sample. They contacted a number of possible participants covering the multidisciplinary spectrum and provided the researcher with their contact details.

In turn, the researcher sent an email, a month prior to the focus group taking place, to the potential participants inviting them to the focus group. The email included all the information regarding the purpose of the focus group, date (19<sup>th</sup> January 2016), time, that it would last for approximately an hour and a half, venue, and a deadline by which they needed to respond to confirm attendance (Appendix J). Attached to the email was also the invitation letter (Appendix K) which explained; the intention of the focus group, what

participation would involve, that the session would be recorded and all data would be confidential.

Confirmation of attendance was received from five participants (11 participants were invited).

### **5.6.3 Data capture**

To ensure all interactions were fully captured, the focus group was digitally recorded. All participants were made aware of this in both the invitation letter and the consent form (Appendix L). Participants were informed of how the data would be used in the same way as for the Jordanian focus group.

The group was chaired and facilitated by the researcher (there was no research assistant present in Malta). All participants provided their names and profession at the beginning of the recording. This information was used to aid transcription only.

### **5.6.4 Participants**

Eleven people were originally approached to attend the focus group. Five people attended in total, providing a multidisciplinary view. A breakdown of participants can be seen in the results section.

### **5.6.5 The focus group set up**

Prior to the focus group taking place, the researcher prepared appropriately in the same way as for the Jordanian focus group. Please refer to the above section for information regarding this.

The room in which the focus group was to take place was a private meeting room. The chairs were set in a circle around a table.

### **5.6.6 The focus group introduction**

The focus group introduction was conducted in the same way as in Jordan. Please refer to the above section (5.5.7) for information regarding this.



### **5.6.7 The focus group in action**

Three participants attended from the start of the group, one just after the focus group started and the last half way through. The first three were all allied health professionals and female. It would be true to say that their level of input was higher when not in the presence of the other participants. Whether this change in contribution was due to indigenous culture, organisational culture or personality is impossible to say. As this was noticed during the focus group discussion, the researcher made efforts to ensure they were continuously kept in the conversation by inviting them to contribute, making eye contact and giving enough time to respond or seek clarification.

As it was a small group, there was greater familiarity amongst the participants. The focus group was conducted in English.

The questions were asked in the same manner as they were in Jordan (please see the previous section), with there being flexibility over the order questions were asked. There was no difficulty amongst participants in expressing answers in English as all spoke English fluently.

The focus group lasted for an hour and a quarter. Participants were engaged and keen to contribute throughout. All questions were covered and discussion was held regarding aspects that were not in the question schedule but which provided the researcher with a further understanding of how the healthcare system in Malta operates.

The researcher thanked the participants for their time and their contribution. The participants expressed that they had enjoyed the experience and were keen to offer any other help if needed.

## **5.7 Semi structured interviews: pre and post guideline development**

### **5.7.1 Semi structured interview questions**

The interviews were held so that an assessment of the cross cultural utility of the PARIHS framework could be made, as well as identifying challenges and barriers to successful cultural translation and implementation. As the interviews were with the participants of the guideline development group, this allowed for an exploration of their experience of the development process and the impact on their understanding, knowledge and views of evidence based healthcare and clinical guidelines. The questions for both the pre and post

interviews were primarily shaped by the literature review and further informed by the focus groups held in both Malta and Jordan. The Maltese focus group was also used to; check for conceptual equivalence, particularly in regards to whether the concepts to be discussed had resonance in the population in which the semi structured interviews were to be undertaken; to check the accuracy of phraseology for the Maltese population and the familiarity of concepts such evidence based medicine.

### **5.7.2 Participants**

The interview participants were members of the guidance development group who had been identified by the head of department; a multidisciplinary group for the treatment and management of obesity. Fourteen healthcare professionals and two patients / carers were invited to attend initially. Nine healthcare professional participants took part in the pre interviews and nine in the post interviews. The head of department provided the researcher with all contact details after he had informed them of the study.

The patient /carers did not attend the interviews or the guideline development group.

### **5.7.3 Organisation of interviews**

The researcher introduced themselves to the participants by email. An introduction email (Appendix M) was initially sent introducing the participants to the guideline development group, outlining the task of guideline development and the dates for the development meetings. It was accompanied with an attachment detailing the research study and how the guideline development was part of this (Appendix N). This was followed by an email inviting participants to the pre guideline development interview (Appendix O), with the pre and post interview invitation attached (Appendix P).

A range of dates and times were given (between the 19<sup>th</sup> and 21<sup>st</sup> January 2016) for participants to choose from, with the option of choosing between 2 and 3 times. The researcher was as flexible as possible in scheduling interview appointments, to ensure the least disruption possible to the participant's working day. Interviews were arranged to be held in the hospital, either in an office of the participant, a meeting room or a hospital meeting space. To accommodate all that wished to participate, one interview was conducted over the phone and two people were interviewed together (pre and post). Participants were informed that the interviews would last for approximately an hour. The

process of sending an email with a selection of dates and times was repeated for the post guideline development interviews.

Best practice suggests that healthcare professionals should be given 6 to 8 weeks' notice to allow for adequate scheduling of a meeting. Due to time constraints experienced because of the process of moving study site, including gaining ethics approval, for the pre interview and the first guideline meeting only two weeks' notice was given. For the post interview and the second guideline meeting, the researcher was able to give six weeks' notice.

#### **5.7.4 Data capture**

To ensure all interviews were fully captured, they were digitally recorded. All participants were made aware of this in both the invitation letter and the consent form (Appendix Q). The consent form also gave the participants the option to stipulate if they did not wish for their contribution to be recorded. The digital recorder was checked for battery life at the beginning of each interview.

#### **5.7.5 Interviews in action**

The researcher used an interview guide and prompts to guide the pre and post interviews (Appendix R). The interviews were recorded and notes were taken as prompts on specific points. When participants spoke but requested not to be recorded, the recording was halted and restarted when requested. This happened at some points during the interview or when the schedule of questions had finished. The interviews ranged from 25 minutes to an hour which was dependant on the participant for some were more forthcoming than others. The researcher made sure that throughout the interviews eye contact was maintained as much as possible and that participants were given time to answer questions in full. Questions were clarified when needed. The interviews were very interactive and relaxed, participants were at ease throughout and encouraged at all times to contribute using prompts to explore areas in more depth when needed.

One pre interview was conducted over the phone. The researcher was fully prepared for this as they had researched factors to be aware of and how best to conduct an interview if interviewing by phone or Skype. It has been suggested that interviewing without being face to face can lessen rapport (Sally, 2016), however this was not experienced. The interview went very smoothly and there were no problems with communication. The researcher

made sure that they were in a quiet place as had the participant. The interview was also recorded with a good level of clarity.

Two participants requested to be interviewed together for both the pre and post interviews. They were happy to work in this way and understood that everything discussed was to be kept confidential between them. One participant was more forthcoming than the other thus the researcher made sure throughout the interview that questions were directed to both and the quieter participant was encouraged to contribute. The participants were very respectful of each other and clearly 'bounced off' of each other.

## **5.8 Development of clinical guidance**

### **5.8.1 Topic identification**

To explore the suitability of the PARIHS framework, for cross cultural translation and adaptation of clinical practice guidelines, an evidence based clinical guidance was to be developed, with the process being informed by the three key elements (facilitation, evidence and context) of the PARIHS framework.

It was of primary importance that the guidance topic was appropriate to Malta and for which there was an identified need. The guidance would be developed by the researcher and a team from the National Guideline Centre (NGC) who have expertise in the guideline development. On completion the guidance would be given to the head of department to implement. Through discussion with two key physicians assisting in the facilitation of the study, it was decided that the topic for guidance would be obesity as this is an area of serious healthcare need in Malta.

NICE guidance: Obesity; identification, assessment and management (CG189) (National Institute for Health and Care Excellence, 2014) was reviewed by the researcher and the NGC team to facilitate discussion regarding suitable clinical questions to be considered.

Two initial review areas were identified and agreed to by the Maltese physicians; pharmacological therapy for the management of obesity and surgical therapy. Following agreement, the team at the NGC created a draft review protocol for each area to be presented at the first guidance development group. Two guidance development group sessions were planned during which the development of the guidance was to take place following the discussion of the evidence presented. The NGC was tasked with carrying out

the systematic reviews of the clinical questions, putting this data into a presentable format and presenting it to the group. The group in turn were responsible for formulating recommendations based on the data presented ensuring relevance to the local context.

### **5.8.2 Formulation of the guideline group / invitation to attend**

Fourteen healthcare professionals and two patient /carer representatives were invited to attend the first guidance development group meeting by email. Unfortunately neither patient nor carer representative could attend. Eleven healthcare professionals responded, providing a representative mix of the healthcare providers needed for the care of obese patients.

The email outlined the purpose of both guidance development meetings and also provided dates for both of them to allow for enough time to plan attendance. Participants were informed that the purpose of meeting one was to cover the methodology of guideline development by providing an overview of GRADE and critical appraisal, interpreting and understanding health economic evidence in guideline development. They were also informed that time would be used to review the existing guideline and recommendations, confirm the review questions and protocols. This meeting was to be run by a methodological expert from the UK and attended by the researcher and a UK physician.

Attached to the email was an outline of the study. All participants were requested to respond to confirm their attendance.

Advice was taken from the Maltese physicians regarding the most appropriate time to hold such a meeting. It was agreed that the meeting would be held between 11 and 2pm on Friday 22<sup>nd</sup> January. As this was over lunch time, lunch was provided.

### **5.8.3 Guideline development group: meeting one**

Eleven participants attended. A consent form (Appendix S) was provided as the session was to be digitally recorded. The opportunity was taken to overview the purpose of the study and highlight the benefit of participating in the development of the guidance.

The first half of the meeting focused on providing an understanding of the way in which the NCG develop clinical guidelines, outlining the guideline methodology to be used to develop the guidance associated with this study. It was presentation based yet interactive to allow for questions. The methodological expert encouraged questions and debate about the

topic area. As participants had a mixed level of research or guideline development experience, the session was run in a manner accessible to all.

The second half of the meeting concentrated on the clinical questions that would form the basis of the guidance. The protocols underpinning the questions were presented and discussed in depth to ensure elements that needed to be covered were accurate and agreed upon by all. The protocol facilitates the systematic review and the format used is based on the PICO process; population, intervention, comparisons, outcomes, but also include other elements such as study design, setting and key papers. The importance of this exercise was emphasised to the group, for once the protocol is set and the systematic review has been completed, it cannot be amended because preferred information has not been provided. It is also a very effective way in which to engage with the group and get them actively involved in designing the reviews. The clinical questions presented and agreed upon were:

- a) What is the clinical effectiveness of pharmacological therapy at reducing the weight of people with severe obesity?
- b) What is the clinical effectiveness of bariatric surgery for people, with type two diabetes, who are obese?
- c) What is the clinical effectiveness of bariatric surgery for people who are obese?

The group were enthusiastic about the questions and contributed to their formation well. They were informed that the next meeting would require them to interpret the data and make recommendations for their healthcare service. Copies of the protocols were disseminated to the group following the meeting.

As the researcher was not presenting during this meeting, they observed and recorded the proceedings. The researcher thanked the participants at the end of the meeting and stated that they and their colleagues were available for further questions if needed.

#### **5.8.4 Guideline development group: meeting two**

The purpose of meeting two was to review the clinical evidence presented by research experts from the UK, from which the committee were tasked to create recommendations suitable to the Maltese context.

Following the input received at GDG1 regarding the protocols, the second guideline development meeting had to be postponed (from the 25<sup>th</sup> and 26<sup>th</sup> February until the 18<sup>th</sup>

March 2016) to allow adequate time for the work to be done as one of the reviews was larger than anticipated. All participants were informed of this change by email:

*“Thank you for all the input you put into the protocols which will underpin the reviews that we do. As the protocols have expanded (and thus so have the searches), we will have to move the date of the meeting”.*

This change not only allowed for a more thorough review but gave an opportunity, for attendees to have further time to make arrangements to attend the next meeting. From discussion with those with whom the researcher was liaising, a decision was made to reduce the meeting from two days to one and hold it from 9am to 3pm.

Disappointingly, only four participants attended the second meeting and one could only attend for half a day. Apologies were received, some of which highlighted the difficulties of a small healthcare service and the inability to arrange clinical cover. With those that attended, it was decided that the meeting would continue and the recommendations would be made. The documentation would then be circulated amongst the whole group who would be invited to comment on the recommendations, allowing participation from all group members.

The reviews were circulated to all participants a few days prior to the meeting. Each review was presented individually by the two research experts from the NGC. Time was taken during the presentations for participants to ask questions and seek clarification. All questions were answered. At the end of each review, discussion was had about the evidence which led into discussions about the clinical recommendations to be made. To help facilitate the process of making clinical recommendations, the researcher presented existing recommendations as examples. This helped stimulate thinking and illustrated how an overarching recommendation can be broken down into smaller parts. For the recommendations please see the full guideline Appendix T.

By the end of the session, draft recommendations were made from the evidence that had been presented with the Maltese context in mind. The researcher thanked all for attending and reminded all that the recommendations would be circulated with the whole group for further input.

The researcher had a more interactive part in this meeting as they were assisting in framing the recommendations. However observation notes were still made.

#### 5.8.4 Next steps of guidance development

Following the second meeting, a further email was sent, explaining the next steps of the guidance development to the group.

*“Please find attached the presentations that were given last Friday, which are supported by the review documents that were circulated. They will support your interpretation of the reviews. The recommendations that were drafted will be sent round with a summary of the supporting discussion, in the next couple of weeks (I’m going to be away for the next 10 days). When I send them, I’d appreciate your comments and feedback. In the meantime, enjoy these reviews and if you have any questions I will respond on my return the week starting 4<sup>th</sup> April”.*

The study was given very strong support by the head of the department and it was agreed between him and the researcher that all work would be viewed by him prior to sending it to the wider group. Therefore the recommendations were sent to him for checking for accuracy and acceptability, changes were made and he returned them to the researcher. Conversations regarding changes were had using email. The same process took place with the finalisation of the evidence reports, which are the full documents that include the systematic review, the recommendations and how these are linked to the evidence. The evidence reports were written by the reviewers and reviewed by the researcher for accuracy. Once completed, the evidence reports were sent to the GDG, with clear instructions regarding what needed to be done, for them to review and comment on.

*“Whilst it is important for you to read the whole report to re-orientate yourselves (and proof read if you like), Please comment on the tables entitled **Recommendations and link to evidence**. This table encapsulates the discussion had about the evidence when it was presented. Therefore, once you have looked at the evidence please do add any other comments, to further substantiate the recommendations made. No additional evidence can be added at this point”.*

It was important to emphasise that no additional evidence could be added for this would be in breach of the protocol. A deadline was given and reminders sent to the GDG prior to the deadline. All comments were incorporated and changes made. The final evidence reviews and recommendations (Appendix T) were sent to the link physicians whose responsibility it was to disseminate the guidance.



## **5.9 Observation and reflexivity**

The researcher identified that observations would focus on the influence of culture on the discussions, the behaviour of the group and an interpretation of the effect that culture has on the use of evidence based practice. These observations were noted during the focus group and guideline development meetings, immediately after and checked when the recordings of the meetings were transcribed. The researcher made sure they noted why a particular observation had been made and whether they felt that they had influenced it in any way. The account is the reviewer's interpretation of events with an acknowledgment of the influence of their own personal beliefs, culture, background and the context (Yin, 2012). Simultaneous to the noting of observations, the researcher kept a reflective diary throughout, documenting all thoughts regarding the process and their role within it.

## **5.10 Language used for the research.**

The researcher did not speak Arabic and therefore all research activities and correspondence was carried out in English. The level of English spoken from participants was very competent, often attributed to many having studied in English speaking countries and stating that English was needed in order to keep up to date with evidence based medicine, journal articles and clinical guidelines. At no point during the focus group did the researcher feel that language was a barrier. Sometimes, the 'wrong' word was used, but this was either corrected by another or did not change the meaning of the sentence. All participants were open to speaking English and did so with confidence. Clarification was given if either the participant had not understood the researcher and visa versa. There was also no barrier towards the researcher conducting this process in English.

Maltese and English are both official languages in Malta, therefore as the researcher did not speak Maltese all research activities and correspondence was carried out in English. There were no barriers towards the process being carried out in English as all participants were open to speaking English and did so with confidence and a good use of colloquialisms. Clarification was given if either the participant had not understood the researcher and vice versa.

## **5.11 Cultural awareness of the case study**

The researcher made sure that they understood and were aware of any culturally specific behaviours, or body language, in both Jordan and Malta. In doing so, the researcher was

prepared for the potential difference in dynamics of group interactions. Prior to carrying out the case study they checked whether focus groups were an acceptable form of practice in both countries and in Jordan, whether it was acceptable for men and women to socialise in this way. Concerted efforts were made to develop rapport and trust between the researcher and participants by; engaging in informal chatting prior to the focus groups or interviews; by giving time at the beginning of each data collection, to clarify and answer any questions and discuss their expectations of the data collection process.

### **5.12 Summary**

In sum, the research was carried out using the methods identified; focus groups, semi structured interviews and observations. These methods were successful in the collation of data and engagement with participants. The data is reported in the following chapter.

## **6 Chapter Six – analysis and findings**

### **6.1 Introduction**

This chapter is divided into two main sections; an analysis of the focus groups and an analysis of the interviews and observations made. Each section is reported under both the themes derived from the literature, in particular relating to the PARIHS framework and also the themes that were inductively distilled as a result of the framework analysis. Direct verbatim quotes are given as examples in some parts to illustrate the themes. As English was not the participants' first language in either country, some non-English words are occasionally used by participants or they do not use a standard sentence construction. They are presented as recorded and the meaning, in the round, is clear.

#### **6.1.1 Carrying out the analysis**

The interpretation of data can be achieved through the use of a variety of analytic software programmes, manually or using a mixture of both. Software programmes have been reported to be particularly useful for the aspects of analysis that are more time consuming and repetitive (Jones, 2007). However, their use should be applied with a level of care (Pope et al., 2000) as a software programme can assist in the organisation of data, and can help facilitate the analysis of data but it cannot actually analyse the data (Zamawe, 2015). That is to say, a programme cannot make the intricate connections needed to convert the raw data into themes and subthemes and create an understanding of the relationships between them (Thorne, 2000). There are proponents of both making the decision of which to use dependant on personal preference.

Data analysis in this study was performed by hand and without the use of an analytic software programme. This method was chosen as it provided the researcher with the ability to map the themes and sub themes as a whole, visualising those that were inductive and deductive simultaneously. This was achieved by the use of spider diagrams, which were drawn with central themes in the middle and sub themes branching off of them. Linkages between subthemes and themes were made by placing the spider diagrams together and moving them around. The themes and subthemes were listed and distilled, with new spider diagrams being created until the subsequent themes and subthemes were arrived at. It is this distillation that is outlined below.

## 6.2 Analysis of focus groups

Two focus groups were held, one in Jordan followed by one in Malta, as the PhD study site was transferred from Jordan to Malta. The purpose of the focus groups were to provide an understanding of the case and inform the development of the interview questions. This section reports the key themes that emerged from the focus groups with a comparison of themes between the two groups. Analysis of the focus group held in Jordan is included, as it was an opportunity to compare data across the two sites, and establish any difference between the responses to the focus group questions. Focus group data will also be included in the overall framework analysis of all components of the case study.

Whilst there are some similarities that are discussed later, the two focus groups also brought up different concepts. To delineate between the two, countries are identified in brackets and concepts are separate.

The following table (Table 5) is a summary of the themes that were identified using framework analysis. This section expands on each theme, using quotes as examples.

**Table 5: Summary of focus group themes**

Theme Jordan	Sub theme Jordan	Theme Malta	Sub theme Malta
<b>1. Understanding evidence</b>	Definitions of evidence	<b>1. Understanding evidence</b>	Definitions of evidence
	Use of evidence in practice		Use of evidence in practice
<b>2. Clinical guidelines</b>	A source of evidence	<b>2. Clinical guidelines</b>	International guidelines and their localisation
	Guideline variance		
	Guidelines as a barrier		
<b>3. The influence of context, culture and the patient</b>	Context: learning environment	<b>3. The influence of context, culture and the patient</b>	Receptive context; learning environment, resources
	Multidisciplinary working		
	Culture		Non receptive context
	The Patient		The patient
<b>4. Facilitation</b>		<b>4. Facilitation</b>	
<b>5. Barriers to the implementation of evidence based practice</b>	Financial resources	<b>5. Resources as a barrier to the implementation of knowledge</b>	

	Resistance to change		
	Workload		
	Access to information		

### 6.2.1 Understanding evidence

Interpretation of the focus group indicated that within the Jordanian setting studied, healthcare evidence was used in practice. In response to the questions asked participants provided definitions of what they understood evidence to be, how they used it in practice and that it came from a variety of sources.

Conversation from the focus group participants in Malta indicated that evidence based practice was common within Malta with a clear recognition of the use of clinical guidelines and the need for practice to be grounded in evidence. Early on in the dialogue acknowledgement was given to the need to implement evidence.

#### 6.2.1.1 Definitions of evidence

**Jordan:** Evidence was perceived as being data distilled from analysis and best practice, with an emphasis placed on the need to gather information from more than one source. Participants summarised this as;

*"I think it is a collection of others' experiences and studies. We use it to approve the subject we are teaching."* (FG101)

*"We can describe it as three circles that are interlinked, that mixes both patient preference with best available evidence and doctors' expertise"* (FG107)

In addition to this, evidence was repeatedly regarded as being a form of '*proof*' that a treatment or drug was effective:

*"To prove something, depending on the data you have."* (FG110)

*"Not just information or data from a clinical situation or a ... this was run on a clinical trial maybe and was like proved or put on the FDA (Food and Drug Administration) or highly prevalent."* (FG109)

**Malta:** Evidence was defined as being research based and expressed in a number of ways in regards to what it was and its function.

*“It is something that you can relate to, there is evidence that I can see or touch or read or something” (FG204)*

*“Proof” (FG201)*

*“It meant that there is direction” (FG209)*

*“Basically in medicine now when you have something which has been studied and trials ... and set up of studies and you have the evidence...” (FG209)*

#### **6.2.1.2 Use of evidence in practice**

**Jordan:** evidence was stated as being used to inform practice and to improve patient care, for example as one nurse stated;

*“I use it to refine the old practices in nursing, that are the new ones that are proved to be, to enhance, and better, more and more nursing”. (FG103)*

**Malta:** the evidence used was said to be dependent on the subject being addressed, which in turn was dependant on the healthcare professional using the evidence. There was however general agreement that guidelines were largely used as evidence across healthcare professions. The integral role that finances have on clinical practice, decision making and their own guideline recommendations was identified as influencing the use of evidence.

*“It depends what the subject, what we are dealing with in that particular instance. I mean guidelines, studies, mostly guidelines though.” (FG203)*

*“It means obviously that you are practicing and what you are practicing is based on the evidence, coming from guidelines like.” (FG203)*

*“Obviously when we are building our recommendations we take into consideration even the financial aspect.” (FG201)*

Participants captured the complexity of evidence and the multifactorial nature of its use in decision making. This was summarised as follows;

*“It’s the knowledge; guidelines, evidence, whatever you are mentioning, then you have to apply to the local scenario. I mean the, the financial aspect you have to take into consideration as well, it’s one of the factors, the patient outcome definitely is another important factor.” (FG203)*

## **6.2.2 Clinical guidelines**

### **6.2.2.1 Jordan**

#### **A source of evidence**

The use of clinical guidelines was seen to be a source of evidence used in clinical practice, they were selected from a variety of sources and it was acknowledged that there was variance in guideline quality.

Clinical guidelines were identified as being used as a source of evidence and applied in clinical practice. Participants stated that they were taken from a variety of organisations and often utilised without question, particularly if they were international and recognised as being from what were perceived as reputable sources. When discussing how one chooses which guideline or recommendations to follow, it was stated that this was informed by an amalgam of factors such as; resources, availability of treatment, patient characteristics;

*“For example we do not use any one just say this one, two, three guidelines you can follow. Some names like the WHO or some other organisation well known for us that you will take these guidelines and you can implement them.” (FG102)*

*“I think the best medicine for the patient is the available medicine not affordable medicine. So by NICE guidelines, by other American guidelines, they offer many drugs which are not available in our country and are not affordable to our patients”. (FG108)*

#### **Guideline variance:**

Conflict amongst guidelines was acknowledged as different guidelines were reported as having contradicting recommendations, resulting in healthcare professionals reporting that they picked their preferred guideline depending on the desired patient outcome.

*“Sometimes you can’t apply this guidelines or if you apply it you will find another results such as your guidelines, the NICE guidelines or the American Heart Association regarding to*

*the hypertension there is some difference sometimes, you use this guideline there is not such a good outcome.” (FG110)*

#### **Guidelines as a barrier:**

As a continuation of this, it was identified that guidelines sometimes act as a barrier to being able to practice. An example given was if one wanted to use a new drug that was available but the guideline did not sanction it. Then it becomes difficult to obtain or introduce. This can in turn influence the decision of clinical leaders, hospital management or allied health professionals, who decide on the introduction of new practices. .

*“So, you need to argue the pharmacist and the other bossey [sic] in the hospital, that you need this medicine to this case and again, guidelines is against this, so this is the negative impact sometimes.” (FG101)*

#### **6.2.2.2 Malta**

In Malta familiarity with clinical guidelines and the use of them to improve practice and the quality of care was evident.

#### **International guidelines and their localisation:**

The importance of local guidelines was discussed and the group drew attention to a multidisciplinary guideline group within the main hospital responsible for developing clinical guidelines which are made available through the hospital intranet. The hospital guideline group has been able to develop a number of guidelines;

*“... from scratch yes. A local, local guidelines ... erm and eh, now we have built up quite a good portfolio of local guidelines”. (FG202)*

Awareness by the hospital’s general medicine guideline development group of the need for multidisciplinary involvement was strong and extended beyond healthcare professionals;

*“And then they will cascade to the nurses. And anyone really who needs to be involved. If it is the caretaker who needs to be involved because someone needs to be wheeled somewhere or whatever, you know, the porter, then we’ll involve them.” (FG202)*

There was also understanding that they do not have the capacity to develop a clinical guideline for everything:



*“Lets say we sort of share a lot of because the capacity here is quite limited and we typically do look at what NICE (National Institute for Health and Care Excellence) has produced and at what the SMC (Scottish Medicines Consortium) has produced on a particular drug.”*

(FG201)

A variety of international guidelines were stated as being used, with a focus on those from national bodies or clinical specialty groups primarily in the UK, EU or the United States. Selection of which guidelines to use was based on the topic, whether it is a specialised topic, and the most recent publication. European guidelines were regarded as being both more recent and having greater resonance with Malta as a fellow European country. International guidelines were recognised as needing contextualising to make them appropriate for use, although there was no definition as to how they contextualised the guidelines

*“I can tell you from my experience. Local, putting them in a local setting is one of the basic requirements of good guidelines.”* (FG202)

The choice afforded by having access to so many guidelines was regarded positively, and the plethora of international guidelines was acknowledged;

*“And I think you know the way it’s been developing internationally over the past ten years, guideline mushrooming from every single association and institute.”* (FG202)

### **6.2.3 The influence of context, culture and the patient**

#### **6.2.3.1 Jordan**

Even though guidelines were generally perceived as being helpful in informing clinical practice, they were identified as not always being implementable or applicable. Reasoning for this was primarily attributed to three areas; context, culture and the patient and the influence they have on the development and implementation of recommendations.

## Context

There was an appreciation that healthcare guidelines are developed within a different context to which they are often applied and thus they were perceived as only having partial applicability.

*“They (the guideline) grow in a different population. They might apply but partially. Just serving as a general guide.” (FG107)*

## Context; Learning environment

There was reference to whether the work context was supportive of learning. The context in which the participants worked was recognised as being one which encouraged the use of evidence based medicine, specifically elements such as continuing medical education and a desire to learn. The opportunity to acquire and develop knowledge was reported as being inherent in the environment in which they worked, with there being numerous work based continuing medical education activities in the form of lectures, meetings, journal clubs and the opportunity for further study.

*“There are always lectures during each department, education meetings and journal clubs as well as all kinds of evaluations and educations so there is always continuing medical education.” (FG102)*

*“You can find meetings and reviews and conferences like this.” (FG110)*

*“The nursing department we have a continuous educational programme, that includes one lecture every week on different subjects.” (FG101)*

*“Each department of the Royal Medical Service has their own programme.” (FG109)*

These reported opportunities were irrespective of the department in which participants worked as it was noted as being the ethos throughout the Royal Medical Services. There was a noted encouragement to undertake further education for extended learning, obtain further qualifications but also to position oneself for a career promotion;

*“... to get next to be specialist or be first senior specialist or consultant, you have to get CME hours, you have to publish some articles, you have to be speaker in many conferences. I think this can stimulate doctors and nurses to get more knowledge in their specialties.” (FG108)*

*“Some of them they have a diploma degree in nursing, they start to develop themselves by having a BA degree. And those who have a BA degree start making Master and some of them starting PhD.” (FG103)*

### **Multidisciplinary working**

With regard to multidisciplinary working, there was a sense that the participants and their colleagues worked well in a multidisciplinary manner, despite working in an inherently hierarchical work environment. It was interesting to note that the group interacted with each other without obvious concern for clinical or military hierarchy. Some education events, like the conference the participants were attending, were also multidisciplinary. Reference was made to participants regarding themselves as being part of a team

*“... we have this team work ... yes team spirit.” (FG110)*

### **Culture**

The influence of culture was shown in regards to the culture of the population and the influence this has on the direction healthcare professionals take in order to be respectful of the culture of the population and their wishes;

*“There are also social and religious barriers in applying guidelines. Because we know that patients should have everything about their disease and about his condition and he has the right to decide but in some circumstance we cannot tell the patient about his condition because his other member of family telling us that it is forbidden to tell him that he has cancer because he will be depressed all day. So I think there is a social and religious balance in applying some guidelines and communications that we have learnt from your guidelines, British or American guidelines”. (FG108)*

This theme is continued in the next quote's reference to 'breaking bad news' being something regarded as an 'art', as it is an indication of an assumption often contained in guidelines that methods of communication are international. This quote suggests that culture influences clinical practice, in this aspect communication, and therefore one may not assume that guideline recommendations, whilst illustrating best practice, are acceptable and applicable in all circumstances. It suggests that the way in which breaking bad news is addressed in the UK does not fit into the cultural or social practices in Jordan, where bad news is often not given to a patient but rather to the family instead.

*“Breaking bad news, it is a piece of art in your guidelines but we cannot break bad news for our patients as you do”. (FG108)*

## **Patients**

Continuing the emphasis on knowing the culture, a number of aspects relating to **patients**, were identified that have an impact on the way that a healthcare professional may practice evidence based medicine. These were noted as being; level of patient education, social class, understanding, economic status, age group, area from which the patient comes from; urban versus rural. An example can be seen in the following quote which relates to the perceived level of a patients’ understanding which was attributed to the patient’s level of education and/or the type of information accessible to them.

*“Patient available education does affect their choices and in turn will affect our management.” (FG107)*

The participants highlighted the significance of understanding the impact of these factors and the affect they can have on the healthcare provider / patient interaction. To manage such factors, participants indicated that they alter the information they give, depending on the patient. For example:

*“It is like individualised practice, so this patient I can tell her, other patient I can’t tell”. (FG107)*

*“I sometimes say to the patient, I can’t pronounce this is a cancer medicine otherwise she will not take the medicine. Or he will not take the medicine. So I have to be so polite, so kinds and not to mention this hard word, otherwise I am harming him”. (FG109)*

This quote is an illustration of the complexities and difficulties of imparting such information. That is to say, it indicates how the healthcare provider needs to recognise and be aware of patient preconceptions regarding medication and treatment and their ability to understand the treatment being offered. It is also an acknowledgment and reminder of the importance of tailoring patient / healthcare provider interactions and the notion that not all patients are used to having full information about their healthcare.

### **6.2.3.2 Malta**

In Malta, context and culture were identified as impacting on how evidence is implemented into practice. A theme emerged of receptive and non-receptive context and the aspects

that contributed to these. Culture was related largely in terms of the culture of politics, however facets of culture can be seen in the sections on patients and barriers to implementation.

#### **a) Context**

##### **Receptive context:**

The importance of a receptive context was referred to whereby the environment was one that was open to learning, guidelines could be contextualised (see above re-guideline contextualisation), resources were available and change was willingly implemented.

**Learning environment):** Participants reported that the hospital supported accessing evidence, continuing medical education and personal development. Nurses were stated as being able to pursue further education up to PhD level, *“we even have nurses with PhD”*. A variety of resources were cited including, the hospital portal that facilitated access to guidelines and policy, access to relevant journals, multidisciplinary education in various forms; seminars and conferences.

**Resources:** It was remarked that resources fell within the arena of a receptive context, as there needs to be sufficient resources, either financial or human for implementation to be successful. Whilst the Maltese context is open to the use of and implementation of new ways of working, evidence and guidelines, and is thus regarded as receptive, the lack of financial and human resources were clearly stated as creating a barrier to achieving this. Linked to resources was the capacity of those that are currently working.

See the section below on barriers to implementation for further expansion on resources.

##### **A non-receptive context:**

Resistance to change and the challenge of a non-receptive context was identified as impacting on the implementation of evidence both in regards to the healthcare professional and the patient. Although the participants reported working within a multidisciplinary format and responsibility for the implementation of new ways of working was across disciplines, it was agreed that opposition to change created barriers to implementation. Resistance of healthcare professionals was seen by the group as manifesting either as a whole department, a group of healthcare providers or an individual, with the acknowledgement that in some medical specialities more barriers were encountered. It was also indicated that, reluctance to change can emulate from the patient

being unwilling to change their medical routine which may be the result of new healthcare practices.

*“Certain people are reluctant to that change ... It could be from nurses side it could be from the patients side to change their routines.” (FG205)*

*“If you want change, if you want to change things, you will change things. If you don’t want to change then you will not change them yourself and you will not allow others to do it. Or you will try and tell others to do it.” (FG205)*

*“It depends on the person, the individual. It’s the person, but there are certain areas where there are an accumulation of these kind of people.” (FG205)*

#### **b) Cultural influence:**

An account of the interaction between the healthcare system and the wider political system was given. This indicated how the two were very closely linked and how they influenced each other. It was suggested that patients also have an influential role in politics as their proximity to politicians was commented on as being instrumental in changing the direction of healthcare. This may be regarded as an example of patients using politicians as levers for change and an indication of the wider culture of Malta.

*“I think you might have to appreciate something else about Maltese set up that sometimes supersedes the need for patient support groups felt in bigger countries. The distance between Jo public and your local MP is rather short. And you know pretty much everyone has everybody’s mobile number. Trust me if you need the mobile number of someone you don’t know in Malta typically he is just 2 people away from you. You know. While in other countries I believe it is like 4 or 5. Em, what I am trying to say is sometimes it is not difficult for patients to make their voice heard. Unfortunately I don’t believe it should be through the MP but that’s the step in some ways it kind of works. Because then it exerts pressure and then the pressure typically comes back on us, you know there is this problem we need to address it.” (FG201)*

#### **c) Patients**

Patients were discussed in terms of their involvement and empowerment within the development and provision of healthcare. As such, their involvement was not reported as being a priority, necessarily having a place or utility. As an adjunct to this, patient

experience was not regarded as an aspect to be considered in the provision of healthcare. The group were aware of the existence of particular patient groups and commented that the number of patient groups is expanding. Participants were cognisant of the importance of patient outcomes and consideration of patient views but it was far from being embedded in practice.

*“Patient groups are a bit few and far between I must say, especially for rare conditions. On the bigger conditions they are bigger and more present like on diabetes for example.”*

(FG201)

## **6.2.4 Facilitation**

### **6.2.4.1 Jordan**

The previous section explored the role of external influences and how these can affect the implementation of clinical guidelines. This section looks at the existence of facilitation within the Royal Medical Services and how new ways of working or change is enabled.

Facilitation as a concept in itself was not raised, but answers to other questions demonstrated whether facilitation exists within the environment of the Royal Medical Services. The Royal Medical Services, whilst being a healthcare provider, is ultimately a military organisation in which change may be implemented as an order and is therefore not disputed or facilitated;

*“And in military sometimes (laughter) like such an order, you are going to change it?!”*

(FG102)

Whilst the above is an example of change occurring in a non-facilitative manner, parallel to this, it was identified that there is a drive to create change and it could be achieved through understanding the contextual constraints, the resistance one may face and thus working with these in mind. For example;

*“When you try to change this it will be very difficult at the beginning, so first you have to convince them that using this is better than using that.”* (FG101)

#### 6.2.4.2 Malta

In Malta, participants acknowledged that there was variance in the levels of engagement of healthcare professionals to facilitate change. Yet, on a structural level, the public health system of guideline and policy making was considered to be a facilitator of change. It was understood that there are healthcare providers who wish to implement change or promote new ways of working;

*“There are people, there are professionals who are quite open to change and they can discuss it but there are other people...” (FG201)*

There were also those who were sceptical of change and tried to block it from happening. This not only highlighted the impact of the individual either those implementing the change or those opposing it, but the need to persevere until change is accomplished. There was a sense that people were prepared to work in this way. One participant stated that implementing change was summed up in Ghandi’s words and that was the view that they adhered to, illustrating resilience and perseverance;

*“First they will laugh at you, then but finally they will accept you.” (FG204)*

The role of the individual was regarded as having either a positive or negative impact, thus determining the success of facilitation. A multidisciplinary method was seen as being fundamental to facilitation i.e. it had to be a mixed team approach, which linked with the appreciation for the need to have a bottom up inclusive approach, harnessing the enthusiasm of individuals to instigate and implement change. Much however was based on what was referred to and understood as being ‘goodwill’ i.e. the willingness of the healthcare providers to undertake extra work or activities out of kindness and above the expectation of their role. This however can lead to confusion as it may not occur in a coordinated fashion and has the potential of clashing with other initiatives that one may be unaware of;

*“There is a lot of good will in the system. There’s a lot of good will you know... So we are trying, we are still trying to organise ourselves in that context.” (FG202)*



## **6.2.5 Barriers to the implementation of evidence based practice**

### **6.2.5.1 Jordan**

The focus group identified a range of barriers to implementing evidence, ranging from; system barriers such as finance and workload, to the resistance of colleagues and ability to access up to date information.

#### **a) Financial resources**

There was a broad agreement that financial constraints are a key barrier to using evidence. An example of the reference to financial resources is apparent in the following quote whereby the reference to economy relates to resources;

*"I think the only obstacle is sometimes economy." (FG107)*

#### **b) Resistance to change**

Implementing new practices and/or ways of working were acknowledged as being stymied through the resistance of others to the introduction of change for a variety of reasons such as; change creates more work to an already busy service, the utility of the change is not always understood, the financial implications of change, access to the means of change are not always present. Some of these barriers are illustrated in the following quotes;

*"Sometimes if you want to change such as behaviour you always find resistance as it is costly and timely than the other one (the current practice). So always the idea of change sometimes you will have resistance and obstacle from the team sometimes. The implementation of a new one (new way of working) that will for example need much time, need much effort, resistance will be always." (FG101)*

#### **c) Workload**

The previous quote identifies time as being a barrier in two ways; a new method may be more time consuming to use and it takes time to undertake the work involved with putting new practices in place. Participants stated that they were already working beyond their capacity and the challenges faced by the introduction of new ways of working can be insurmountable. It was intimated that healthcare professionals were working above their optimum capacity;

*"But you know we work for like 8 hours and spend 9 of them working." (FG101)*

There was also acknowledgment of the existing effect that workload has on the provision of healthcare;

*“Workload does affect the quality of a service and delivering the best healthcare to people.”*  
(FG107)

These quotes recognise that workload is already demanding (and in some cases over demanding), thus making the additional work involved with carrying out a new work practice a challenging prospect. A balance is needed between current demands and any future demands imposed by the introduction of a new practice, concept or way of working.

#### **d) Access to information**

Despite it been reported earlier that the work environment is one in which continuing medical education is well supported, the ability to access information was described as being a barrier to furthering education. Participants reported that there is limited access to journal articles other than that which is available freely online. It was acknowledged that it is possible to access articles at work but due to daily workload, there is no time to do this.

### **6.2.5.2 Malta**

#### **Resources as a barrier to the implementation of knowledge**

Resources were identified as being the largest barrier to change and having the biggest impact across all areas of healthcare. The way in which they were expressed was principally related to Malta being a small country. Resources were emphatically defined as human resources (people) and financial resources in regards to the hospital and overall provision of healthcare, medical resources such as availability of pharmaceuticals. A unique factor relating to financial resources was identified as being the inability to procure large amounts of resources because the population is small. It was felt that this restricted them from being able to purchase in bulk at competitive prices.

Linked to human resources was the capacity of people who are already overloaded, taking on more work or what would be perceived as being more work brought about by the introduction of new ways of working.

The following quotes indicate the impact that being a small country has and the restraints that this causes in relation to the delivery of healthcare provision;

*“In a larger setting, human resource, typically equates with funding like if you have funding you can sort the human resource problems but we have situations here that even if you throw money at the problem you do not find the human resource to take it up because there might not be personnel yet trained in that area etc etc so erm, it’s a limited HR pool at the end of the day so there is that difficulty as well as a barrier if I may add it to the list.”* (FG201)

*“So you know the financial restraints are substantial especially given that we do not have the economies of scale to be able to negotiate with manufacturers to obtain, it very rarely happens that we strike gold.”* (FG201)

*“There is also a certain inertia because of financial constraints.”* (FG203)

A lack of a centralised guideline development body, whose role was to develop guidelines was also identified.

#### **6.2.6 Comparison of the two focus groups**

As two focus groups were carried out in different countries, the opportunity was taken to draw comparisons and differences between them. Despite being in different countries, minimal variation between the responses to the focus group questions was found. There were similarities in the groups’ understanding of evidence for example, it was interesting to note that both focus groups, used the word ‘proof’ to define evidence. The way in which proof was used, expressed a desire to have a definitive, documented reason for introducing change. There was a sense that without such clarity then change would not be able to occur, resources would not be made available, and senior leaders would not support it. There was the inference that participants could not just put across a verbal argument but hard evidence would be needed for the process of change to occur. The need for tangible proof to substantiate reasoning underpinning changes in practice was an illustration as to why both groups, in their own way, were supportive of the use of evidence based guidelines. The idea of the contextualisation of guidelines is an added layer in making a solid foundation on which to place such an argument, whilst increasing the applicability of the guideline. This was highlighted in both focus groups as they understood the utility and need for guidelines to be context specific.

Using clinical guidelines was identified in both groups as being a normalised embedded practice. The overall impression given was that whilst there may be too many clinical guidelines to choose from and there was not identification of how choices were made, there is not the infrastructure in either country to enable the production of their own to the extent that would suit the needs of the country. Choice of which guideline to use was then reported as being made based on factors such as best fit, most accessible or most up to date.

Facilitation was regarded as being organisationally led by both groups, thus placing responsibility primarily on the system. However, in Malta it was also seen as coming from a person / people.

Workload was identified in both situations as being restrictive and in Malta was attributed to a lack of human resources and an already overworked workforce. The Maltese focus group identified a number of resource orientated barriers however the Jordanian group did not place the same emphasis on resources, either financial or human. In the Jordanian focus group, culture was referred to on a number of occasions and the restrictions it causes were clearly articulated. In Malta, the attention was more on the context i.e. Malta and the multifaceted consequences of being an island with a small population.

The influence of politics was strongly identified in Malta but not in Jordan. In the Maltese group there was identification of not only the influence of politics in healthcare but how patients can influence politics. This was not evident in the Jordanian group, which may be due to the fact that the group were primarily composed of army personnel and the influences on the provision of healthcare is different.

### **6.2.7 Summary**

In sum, the focus groups achieved their purpose which was to provide a background and an understanding of the healthcare systems in Jordan and Malta and an opportunity to check phraseology and concepts. The focus groups in Jordan and Malta provided an opportunity to explore the meaning of evidence, the participants' understanding of how it related to their work, how they used healthcare guidelines and the barriers associated with the implementation of new ways of working. There was an emphasis on evidence being easily used and for it being a means of providing the proof to underpin any new initiatives, an acknowledgement that they worked within environments that facilitated learning, the difficulties of having an already demanding workload and the pressure of resources.

As the case study was to continue in Malta, contextualisation of why obesity had been chosen as the guideline topic was also provided as the group spoke of the scale of the problem of obesity in Malta and other activities, policies and programmes that were taking place to address it.

Participants confirmed that the terminology used by the researcher, such as evidence based practice was the same in Malta as in the UK, an important step to avoid misunderstanding during later stages of the research. The opportunity was taken within the focus group setting to gain a good understanding of how the healthcare system in Malta worked and the relationships between the department of health, public health and the hospital systems. Funding was also discussed and the huge impact that this has on the provision of patient care. As the topic of obesity had already been identified, the group provided an opportunity for the researcher to understand the extent of the problem of obesity within Maltese society, establish a comprehensive understanding of the healthcare systems and be aware of recent government interventions and Acts. .

## **6.3 Analysis of Interviews: PARIHS framework**

### **6.3.1 Introduction**

A series of pre and post guideline development semi structured interviews were held with the guideline group members to explore the cross cultural utility of the PARIHS framework. This section presents the themes that were identified from the interviews through the framework analysis relating to the three main elements of the PARIHS framework; evidence, context and facilitation. As the framework analyses progressed, wider themes were distilled and amalgamated to create more focused overarching themes and subthemes. These were used to illustrate and understand the function of the elements of the PARIHS framework in a cross cultural setting, providing insight into their utility in a culturally diverse setting. Therefore, a further section of 'culture' was added to the themes. Insight into how these factors interlink with one another is also provided, presenting a dynamic view of the elements.

The analysis of the interviews is divided into the following sections with each theme identified discussed. These themes are illustrated in Table 6.

**Table 6: Themes identified from the interviews**

<b>A. Evidence; what constitutes evidence and its applicability</b>	<b>B. Context; how where we work impacts on what we do</b>	<b>C. Culture; the multifaceted influence of culture</b>	<b>D. Facilitation; and the role of implementation</b>
Applying evidence with caution	A receptive context	Culture of patient involvement in care	Leadership; key opinion leaders
Lack of evidence	A non-receptive context and role of the patient	External influences	Role of the individual in the implementation and utility of guidelines
Guidelines as a form of evidence and the role they play	Implementation of new initiative	Work culture	Stakeholder involvement
Reasons for using guidelines	Sensitivity to context	Learning culture	
	The need for a coordinated approach	Society culture	
	Resources: the impact of human and financial constraints		
	Political influence		
	Patient involvement in healthcare design and delivery		
	Multidisciplinary working		
	Workload		
	Communication		
	Service delivery		

### **6.3.2 Evidence; what constitutes evidence and its applicability**

An understanding of the meaning of ‘evidence’, why it should be used and how it is related to healthcare practice was exhibited by all participants. There was an overriding keenness to use evidence and illustrate that healthcare practice could be changed and improved through its application.

*“I will reflect on my practice to standards and to guidelines and I will modify my practice according to the best available knowledge that there is at the time.” (IB09)*

Being a healthcare practitioner who uses out of data methods and knowledge was voiced as a negative behaviour and as putting patients at risk. There was an understanding of different types of evidence, the difficulties in interpreting evidence and the risk of bias. Findings reported that the drive to change practice and to seek evidence was to be able to provide the best available care for the patient. The following quotes illustrate thinking and reasoning behind the use of evidence in clinical practice:

*“Why am I choosing it, because evidence is showing me that this is, the patient’s going to benefit.” (IB05)*

*“if you don’t base on something and then you base on something you have studied 20 years ago, then that’s a fault ... At the end of the day and that could even compromise safety ok of patients, so it’s very important that one is well, em, acknowledge and is well acquainted with evidence base in his or her field.” (IB07)*

*“I think you have to be humble enough to seek answers when you are not 100% sure.” (IP03)*

*“Decision making I feel in this day and age should be backed by medical evidence. I feel this is in the best interest of the patient and in the best interest of the clinician really because when you back your clinical decision making process with em, results from available research, you are less prone to make mistakes.” (IB03)*

#### **6.3.2.1 Applying evidence with caution**

Whilst there was a clear and expected articulation of the reasons for using evidence in clinical practice, awareness was exhibited that evidence should be questioned and used with caution. There was an inherent understanding that evidence is not an infallible concept. Participants used the rationale that evidence is often from a specific population, exclusive to a very particular group, set in a controlled environment which may not be completely relevant to the context in which it is being applied. This did not prevent it being used but was expressed as an acknowledgment that the context in which studies are carried out differ from the environment in which the results or findings are to be applied.

*“The real world is different from the world of studies.” (IB01)*

Stemming from this is the acknowledgement and indication that evidence requires contextualisation, noting that it cannot be taken for granted that it is relevant to the

population to which one is addressing or to the individual in clinical practice. Thus relating to the need to use evidence with an element of caution.

*“Somebody did a study on a selected population so it may or may not always hold true for the actual patients we see.” (IB08)*

The rationale for regarding evidence with caution was also applied for the following reasons; not all evidence is of the same quality and this should be ascertained before using it; where there is evidence, it should be used in conjunction with clinical judgement or as an aid to decision making; one has to be prepared for evidence to oppose clinical experience.

*“It’s important to get evidence but medicine is not a cookery book sort of activity, you just look, what do I do now. Otherwise you wouldn’t need individuals, you’d just need a computer. You just sit in front of a computer. You put the data, what should the management be?” (IA09)*

*“I think that the trick is understanding what the limitations of that evidence are. That there is evidence and evidence. There is grade A evidence and there is grade C and grade D evidence. And I think not all evidence is of the same level, sadly enough. And not all evidence can be through meta-analysis and double blind placebo control studies. It’s not always possible to get that type of evidence. So I think evidence base is a useful benchmark to try and achieve but it’s not the, either the evidence isn’t there sometimes or the evidence is flawed. I think you have to be careful.” (IB02)*

*“I mean if there are no good studies or good guidelines, then you have to go on what you see in clinic. The only problem is unless you at least audit what you see, you can tend to get a skewed opinion of what’s happening. Because basically you remember the bad things (yes), you know or the patients who are not compliant, or the patients who are really badly controlled rather than...” (IA03)*

*“Evidence base should always take precedence over non-evidence based and eh I mean yes, clinical judgement come in but I don’t know, I’m a person who just believes in, if the research is done well then it will trump any personal experience and personal experience might just be because their set of patients is different.” (IA08)*

Whilst the above quotes refer to the perceptions of how evidence should be used, they also allude to the dynamics of clinical experience and judgement and the variation in attitudes towards the way in which evidence, clinical experience and judgement should



work. There was varying opinion about whether clinical evidence should take priority over clinical judgement (as stated above), whether nothing can trump clinical judgement or a third perspective of a more blended approach of using clinical experience and scientific evidence.

*“Evidence should never replace clinical judgement and common sense.” (IB01)*

*“Don’t practice on your experience only or on case studies but on scientific evidence.” (IB02)*

#### **6.3.2.2 Non-research based evidence**

Consistent with the explanation provided above, clear definitions and understanding as to what constitutes non research based evidence were provided across the multidisciplinary group. Non research based evidence was seen as being; anecdotal evidence, consultant opinion, personal opinion. The following quote illustrates the role that such non research based evidence can have and why it should not always be viewed negatively.

*“There is a sort of reassurance that even in the absence of published evidence the discussion is a bit of evidence in itself, also it’s a sort of Delphi type of exercise. Yes, the collective evidence of experience rather than ‘not, this is how I do it’. I think that’s also useful” (IB09)*

This quote is also an example of how evidence from clinical experience is tested by healthcare professionals through discussion with each other. A research process ‘Delphi exercise’ is applied to this description, perhaps applying a robustness to it and therefore making it more acceptable as it has a methodology associated with it.

For some, the use of this type of experiential evidence was regarded as a risk particularly if used in the development of healthcare guidelines. Reasoning given for such caution was that there was a perception that the more vocal healthcare professional would be more likely to succeed in having their opinion considered.

#### **6.3.2.3 Lack of evidence**

It was acknowledged that research evidence is not always available due to a paucity of evidence in many areas of clinical practice. This implies that clinical decision making is made based on other factors such as clinical experience, knowledge and judgement. Whilst a lack of research evidence may be regarded as challenging by some this was not seen as a reason not to carry out a certain practice. There was a sense that assumptions should not

be made about a healthcare practice just because there may not be evidence, highlighting that a lack of evidence was not the same as evidence showing that a particular treatment or practice is not effective (or even harmful).

*“If there is no evidence that something works, it shouldn’t be taken as being equivalent to being evidence that it doesn’t work.” (IB01)*

#### **6.3.2.4 Guidelines as a form of evidence and the role they play**

Guidelines were repeatedly referred to as being a form of evidence with participants indicating their wide use within the Maltese healthcare system. Access to guidelines was regarded as being easy with a predominant use of guidelines from Europe, the US and Australia, with continual referral to international guidelines. Clear rationale for use was that whilst there are some local Maltese guidelines there are not enough or enough resources to develop them. Utilising guidelines from overseas was reported as being an accepted practice;

*“We have some local ones and then we tend to use the English guidelines so NICE, SIGN sometimes, erm and endocrine we do tend to use the occasional American one, although we tend to adapt one to the other.” (IB08)*

*“We look mostly at the NICE and SIGN guidelines locally and the European guidelines.” (IB03)*

*“UK, American and Australia, those are the big three.” (IB07)*

*“So here we use a lot of guideline from international. We are moving towards something which the UK hasn’t really developed yet which is these integrated clinical pathways, which is I think novel for Malta.” (IB09)*

Whilst it was apparent that guidelines are used from a number of international sources, it was acknowledged that even though the same evidence is being used to develop the guidelines, different recommendations can be made;

*“If you go to the British, European, American, they are not identical, they are not, I mean, they are not totally different but for any condition, you find different guidelines by different societies and they are all interpreting the same evidence.” (IB01)*

This is an example of how evidence is interpreted according to the context in which the interpretation occurs. It was reported that the evidence base of guidelines is not always questioned and they are applied acceptingly. Utilisation of healthcare guidelines without adapting them to the local context was stated as occurring, even though there was awareness that this was not optimal. There was an understanding that adaptation to the local context was preferable, particularly if one took in to consideration the local environment, finances and local evidence. The findings suggested a lack of resources was the reason for the lack of contextualisation occurring. In this context, resources were seen as the means to appraise the evidence and adapt it to the local context. The following quotes illustrate the understanding of the need to adapt guidelines to local context;

*"It's not as simple as applying it locally, just copy pasting , there needs to be evidence, there needs to be research on the local situation to assess whether the same guideline with exactly the same parameters would be good for Malta as well." (IB02)*

*"We use local guidelines especially when it comes to antibiotic use, for example we use local ones because that's what incorporates resistance." (IB04)*

*"It needs to be based on the local situations. So if there is a different prevalence, if people are susceptible to something different, if the environment is different, that will change. I meant it depends what the guideline is but in general, it's always important to adapt guidelines to local use." (IB02)*

*"It's the knowledge; guidelines, evidence, whatever you are mentioning, then you have to apply to the local scenario. I mean the, the financial aspect you have to take into consideration as well, its one of the factors, the patient outcome definitely is another important factor." (FG203)*

The guidance document was regarded by some as being an enabler for change. The reasons given were that the guidance presents evidence in a clear manner, making it an accessible tool which can be used by healthcare providers or policy makers, to inform those with the ability to initiate or fund change. This was not about the quality of evidence but about the ability to access it in a way that makes it understandable to others.

*"I mean if one of the aims to do a guideline is to help in this I think it will make a positive change. At least you have something documented which usually administrative people*

*wants to see something written down and not just spoken, so I think from that sense yeh, I think it would be very positive to do a guideline like this you know.” (IA04)*

In line with the above was the recognition that aspirational recommendations, which are recommendations that may not be immediately achievable as human or financial resources, medications or treatments may not yet be available, are worth making as it leaves an open path for when circumstances change in the future to enable these recommendations to be achievable.

*“So that in a way will applying pressure that there will be introduced but obviously leaving it open because they are not yet available.” (IB01)*

*“If you don’t have the people to do what you recommend obviously, its still good to have it as a goal; this is what I want to arrive at eventually. It might not be doable now but it might be doable in a few years time. So, I mean, that’s how I think things should work, this is what I want to be, but now what do I need to arrive that at my final goal.” (IA09)*

Findings suggested that there was a level of distrust over the use of health economics in guidelines because there was concern that consideration of financial resources may distort treatment decisions and thus not allow for the ‘best’ treatment to be applied. It was therefore recognised that whilst no system has infinite resources, using economics to lead clinical decision making as opposed to clinical evidence or judgement was questionable in regards to whether this was best for patient care.

*“One of the major criticisms of NICE is that their economic, health economics behind them. Which I do understand, as every state has a finite resource but then I am not sure you are always offering the best treatment available or recommending the best treatment available.” (IB03)*

Limitations of using guidelines was expressed in equivalent terms to that of using other clinical evidence, that is to say, that guidelines do not cover all scenarios and need to be used in conjunction with clinical acumen;

*“Guidelines are guidelines, that’s why they call them clinical guidelines and not protocols so we have to use clinical judgement... And then no guideline will predict all clinical scenarios, it’s impossible.” (IB01)*

*“Guidelines don’t normally cover the extremes, however common things being common, as more and more guidelines come out I think particularly for the specialities, the common thing basically. I think they are a good framework to start off with but obviously they don’t replace clinical acumen and clinical thinking process.” (IB03)*

#### **6.3.2.5 Reasons for using clinical guidelines**

Participants provided clear justifications as to why clinical guidelines were used in healthcare. A variety of motivations were identified; to guide clinical practice, whereby it was noted that some may use them as supporting their decision making whilst others may use them to facilitate their clinical decision; as a stimulus for change whether the focus is on a change of practice, service delivery or provision of a drug; as a means of standardising care across departments and reducing conflicting advice between healthcare professionals and to patients; and as something to aspire to, whether individually, as a department or as a system as a whole. They positively identified with using clinical guidelines and saw them also as a way of facilitating a more systematic approach to the provision of healthcare.

*“We use them a lot to back up if we need a drug on the formulary for example. We use NICE to back us up, we say the NICE guideline has approved the use in these particular patients but we are way, way, way backwards” (IB04)*

*“They are hearing one thing from us and then hearing other things on the wards. Conflicting advice, conflicting advice.” (IB05)*

*“A guideline will help you, I mean, to have a more systematic approach to your clinical practice.” (IB07)*

Attitudes towards guidelines were positive but participants were realistic about their effectiveness recognising that they have no effect if they are just a standalone document. There was an appreciation that in order for guidelines to be effective, action needs to be taken to implement them. Participants reported that the hospital’s guidelines were accessible to them on the intranet and some activities were undertaken to educate or encourage their use but not enough for overall change to occur. It was articulated that for change to happen, there needs to be all the elements of a workable service; human resources, financial resources, infrastructure, implementation plan, engagement with decision makers and a whole systems approach. In addition to these aspects, it was noted

that without contextualisation recommendations may be non-implementable particularly if the recommended pharmaceuticals or services do not exist.

*“The guideline on its own is going to be a paper stuck on the wall. We actually need the service, we need the infrastructure, the resources, the manpower, the finances. So the guideline on its own will not change anything.” (IA08)*

Participants were clear that one of the main drivers that restricted the use of guidelines was resources, both financial and human. Without these and thus the service that often is needed to underpin the recommendations within a guideline, implementation to its full extent will not occur. The section within context entitled Resources; the impact of human and financial constraints looks further at the impact of human and financial resources.

*“It needs to be costed, it needs to be prepared. I mean, we said you need dieticians, you need nurses, we don’t have this kind of infrastructure. We don’t have enough dieticians as it is, let alone for a new service. We are severely lacking nurses. So something like this is not as easy as putting up a guideline then we suddenly have the service.” (IA08)*

#### **6.3.2.6 Summary**

The above illustrates that there was a clear appetite for using evidence in practice, with reasoning indicating that it was not possible to practice without it, there was also appreciation regarding the pitfalls that are associated with different types and varying quality of evidence. Guidelines were categorised as being a useful form of evidence yet they need affective implementation and an evaluation of their quality. Recognition was given to how evidence can be interpreted by different audiences, thus supporting the need for the contextualisation of guidelines and therefore this research. Many of the factors covered in this section are linked to other key themes such as context, culture, resources, barriers and enablers, and shall be further outlined under the corresponding sections.

### **6.3.3 Context; how where we work impacts on what we do**

#### **6.3.3.1 A receptive context**

A receptive context, where healthcare professionals are open to change, for example the introduction of new ways of working, was noted as an important factor in the implementation of guidelines but was seen as being variable across clinical departments

and healthcare disciplines. Whilst disparities relating to the uptake of new initiatives or guidelines were identified between departments they were also noted within departments too, making it challenging to implement change. Reasons for the reluctance to change were stated as being the lack of desire to change old ways and concerns that the new way of working would result in more work. The latter was felt so strongly that it was reported as resulting in healthcare professionals contacting their Union as a reaction to the change, as the following quote indicates;

*"... it takes a long time to convince people that by using this guideline things will be improved. So first, because they are always used to using the same methods... and if the guideline means more work for example, we've had instance for example where for example we did some guidelines and we have Unions coming up because of more work for example or because a major change needs to be implemented." (IB04)*

Comment was however made that one may start out reluctant to implement change but after it has been illustrated that the change has a positive effect, then engagement is achieved.

*"If enough people subscribe to them and they are shown to be useful, then I think they will be taken up." (IA03)*

#### **6.3.3.2 Receptive context and the role of the patient**

Reluctance to change as outlined was not just attributed to healthcare professionals. Respondents indicated that a receptive context is also influenced and reliant on the role of the patient and their attitude. It was identified that patients can sometimes be unwilling to change their health behaviour or accept an alteration in their healthcare management, thus causing a barrier to change. These behaviours not only were regarded as affecting the patient, but the ability of the healthcare professional to manage the patient in a preferred or new way. The subsequent quote summarises the different influences of reluctance and the difficulties that can arise;

*"Which is, certain nurses, certain people are reluctant to that change, which will cause others that will really need or really want to move to this desire change to be very difficult. It could be from the nurses side it could be from the patients side to change their routines ... and from the medical side as well. Sort of sometimes we get stuck in what we know best sort of ... and we are afraid to move further." (FG205)*

### **6.3.3.3 Implementation of new initiatives**

Regardless of the recognition that a disinclination for change may exist, findings indicated an appetite for the implementation of new initiatives and ways of working. This was not only expressed through the interviews and focus groups but observed during the discussions of the guideline and the potential for change. Efforts to implement new ways of working or engage with change were reported as being on an individual level or as a department, for example an individual might put together a guideline and lead on its implementation within a specific department. Participants reported that these types of activities and behaviours were often dependent on the individual and have a strong element of being personality driven. This was linked to harnessing the enthusiasm of others and ensuring the right stakeholders are involved (see section 6.3.5.3).

### **6.3.3.4 Sensitivity to context**

The importance of the necessity to contextualise guidelines was a strong theme. Consideration of the context, the macro and micro healthcare environment, in which healthcare is delivered as having its own nuances, was recognised by participants who proffered that the content of guidelines should be modified to reflect the local context. Participants advocated this to be the case particularly when related to specifics such as diet, antibiotic resistance, the availability of items such as pharmaceuticals and services. Concern was expressed that without contextualisation the guidelines would not succeed. Observations were made particularly in the guideline discussion group of the importance of the contextualisation of the guideline. A good example of this was the discussion regarding BMI and how the current level recommended in the UK would not be possible in Malta as there were too many people with a BMI of that level. Thus the recommendations made were with this salient point in mind (these can be seen in Appendix T).

*“Putting them in a local setting is one of the basic requirements of good guidelines.”*  
(FG202)

*“So if there is a different prevalence, if people are susceptible to something different, if the environment is different, that will change. I mean it depends what the guideline is but in general it’s always important to adapt guideline to local use.”* (IB02)



### 6.3.3.5 The need for a coordinated approach

Participants reported that even though there was a coordinated approach in the hospital towards the development of guidelines, through the existence of a guideline group, this did not prevent individuals, within departments or wards from creating their own guidelines. It was acknowledged that this was changing as was the reluctance to adopt the guidelines from the medical department in the hospital. Although the group is from the medical department they were keen to state that a multidisciplinary approach was taken to developing guidelines as there is an acute awareness that for any guideline to be used, collaboration is needed. This supported the role of having a multidisciplinary group for developing this guidelines. However, it was observed that within the group, not all participants were accepting of the development. Change was seen as being facilitated by multidisciplinary involvement and was identified as being important to the development of guidelines or policies and their implementation. It was revealed that this way of working and inclusion in particular of allied health at all levels, could be and needed to be improved.

*“By being involved, you actually have your say how you want these guidelines to be.” (IA09)*

*“I personally was never involved in formulating guidelines before, so the guidelines were there and we just have to follow them, so being present in this group makes you realise how important it is to go on evidence based studies and data.” (IA05)*

*“And anyone really who needs to be involved. If it is the caretaker who needs to be involved because someone needs to be wheeled somewhere (laughter) or whatever, you know the porter, then we’ll involve them.” (FG202)*

### 6.3.3.6 Resources; the impact of financial and human constraints

Resources, both financial and human was a strong theme relating to the context in which healthcare professionals function. They are discussed separately here although it is evident that they have an effect on each other.

**Financial:** A lack of financial resources was recorded as being a barrier to the provision of care, particularly in regards to resources for new staff, medication and new healthcare interventions including lifestyle interventions. The availability of and securing of financial resources was commonly mentioned and noted that without either, it would not be possible to implement the guidance. The ways in which financial resources could be secured was referred to often, linking it to politics, suggesting the involvement of the

Ministry of Health and other politicians, and increasing the awareness of those with financial responsibility within and outside of the hospital.

*"I think, I mean we really need to organise the staff before you can actually implement the guidelines. I mean somebody needs to sit down and finance the whole thing and make sure that the staff are around. There's no use implementing a guideline and saying you need a psychologist post op and you don't find one." (IA03)*

*Now the politicians will come and say, I don't have the money, I don't have the money, but they'll say they are on the NICE guideline as well." (IA09)*

*"Now the problem with politicians is that they see only the short erm, erm, and that's not an easy problem to solve." (IA09)*

*"Finance, obviously that is the first, as is the first barrier, it's the first, cost to implement them, you know financially it has to last for many years" (IB06)*

*"Its all going to come to finance. A report is always going to come down to finance; budget, budget, budget." (IB05)*

**Human resources:** The lack of human resources was considered to be as great, if not a greater problem as financial resources. Concern was expressed by participants that Malta had already reached the point at which there were no more available human resources. Reasons given for this were; the population of Malta is small and therefore there is a restricted amount of people to become healthcare professionals; it takes time to train people; there is a level of attrition as some leave Malta and work overseas or move into the private sector. It was disclosed that in many areas of healthcare professions, the health service in Malta is below the recommended complement of healthcare professionals by the World Health Organisation. Solutions were being sought such as making it attractive for Maltese healthcare professionals working overseas to return, employing healthcare professionals from overseas, identifying new pathways of care in an attempt to streamline the care needed. These challenges underpin the importance of considering how human resources can best be used, how the system can adapt in order to work with less and how an assumption cannot be made that human resources are an endless resource.

*“when it comes to evidence based practice in terms of human resources, then it’s a totally different scenario because if you don’t have the right compliment of people, ok then you can never do the evidence based practice.” (IB07)*

*“It would make it easier if I could, if I had the right staff complement. It would make it much more easier.” (IB07)*

Participants expressed frustration that as individuals and departments they want to improve, and embrace new ways of working such as the incorporation of guidelines or models of delivery of care, but the human resources do not exist to allow this to happen. It was acknowledged that this lack of resources places restrictions on service provision and the development of services. Concern was expressed regarding how recommendations identified in the guidance could be implemented as they were seen as being resource intensive. Aspirational recommendations i.e. those that recommend something that may be regarded as unattainable in the short term but possible in the long term with investment, were acknowledged as being of assistance and important to help move the service in a positive direction.

The following quote illustrates this frustration as it refers to a department that has no further capacity:

*“...Are very keen to be involved, my experience is but again they are very severely understaffed. So erm, they would want to take it up but they obviously have problems with coping with the case load because they can’t cope with the present load, so it requires staff recruitment.” (IA09)*

*“You can’t expect the same number of people and they do more and more stuff” (IB09)*

A concerning finding was that there are services within the hospital that rely on one person. Participants recognised this as a risk in regards to the sustainability of the service, as it was stated that if something happens to the individual or they decide to leave then the whole service fails.

#### 6.3.3.7 Political influence

Access to politicians was perceived by some participants as an effective way to influence and drive change. Participants stated that this was not difficult as both patients and members of the healthcare profession were able to contact politicians. The following quote illustrates this clearly, expanding on political accessibility and context / culture; *“I think you might have to appreciate something else about Maltese set up that sometimes supersedes the need for patient support groups felt in bigger countries. The distance between Jo public and your local MP is rather short. And you know pretty much everyone has everybody’s mobile number. Trust me if you need the mobile number of someone you don’t know in Malta typically he is just 2 people away from you. You know while in other countries I believe it is like 4 or 5. Em, what I am trying to say is sometimes it is not difficult for patients to make their voice heard.”* (FG201)

*“So it’s a political party to introduce new medicine, because people want new medicines, that’s going to come. And that’s what came.”* (IB02)

Participants identified that government engagement and that of the Health Secretary and policy makers was a necessity for funding to be made available. Engagement was also deemed necessary as a means of educating politicians about the long term risks of chronic conditions such as obesity and the financial burden associated with them.

*“Have to be presented to the politicians and to the GFLAC (Government Formulary List Advisory Committee – the committee responsible for advising which medications should be added to the list)...to actually approve it and then start thinking about developing the service”.* (IA08)

#### 6.3.3.8 Patient involvement in healthcare design and delivery

Findings suggested that in Malta, patient involvement in the development of healthcare policy or guidelines is not a regular practice and is not at a level whereby it could be seen as a norm. Such involvement is currently sporadic but was reported as evolving, which was evident in the way in which some healthcare professionals spoke when asked about the involvement of patients. Reasoning for a lack of involvement were mixed, mirroring the diverse views of the participants; patients were thought of as not having the ability to be objective and thus biased; disinclination by healthcare professionals to involve them in

anything that was regarded as being 'technical'; a perceived patient driven reluctance, that they, the patients, feel they do not have the ability to contribute; a disregard for the intellectual ability of patients.

*"... the Maltese are a bit difficult as patients I think, but even their intellect is not quite so high ... they don't even want to know if they suffer from a medical condition."* (IA01)

*"it depends on what type of patient you get ... it depends on their education level..."* (IA03)

Respondents described characteristics that they regarded as necessary for successful patient involvement, emphasising that participation was dependant on the type of patient. The main focus of attention about whether patients should be involved was the perceived level of patient knowledge and education and whether they have a medical background or not. Coping ability of the patient was raised, with concern expressed over how a patient would cope with being a part of such an exercise. Concern was expressed about equity of the patient voice as it was said that the more vocal a patient or patient group were, the more attention and resources they received and the more others are marginalised. This fed into the reluctance to involve such groups.

*"There are some patient groups erm and these patient groups they work on a, if you scream loud enough we'll get what we want."* (IA08)

#### a) Positive engagement of patient involvement

Attitudes of some participants towards the involvement of patients in the development of healthcare policy and guidelines, was positive and enjoyment was expressed in having the opportunity to involve them. Positive body language was observed when some of the healthcare professionals interviewed spoke of their engagement on a collaborative level with patients. The general sentiment was that patient involvement will eventually snowball and people will get more involved over time. It was noted that improvement could be seen in some departments and there was recognition of the patient journey and the need to identify it and give patients a voice.

*"I still think it's good to involve patient societies and also because by involving them more and by them gaining more knowhow, they em, will be in a better position to fulfil, what I believe is their primary role, in patient advocacy."* (IA09)

*"Clearly if it is a patient centred service then you have to listen to the patients."* (IA02)

*"I consider patients as being part of the healthcare team. Sometimes as professionals we only look at the scientific things and I think that the voice of the patient is important."*

(IA07)

b) When involvement should occur

For some however, the value of patient involvement was not really accepted, resulting in comments about the stage of policy or guideline development at which patients should be involved, rather than seeing involvement as a continuous occurrence. There were differing opinions on when this should be; from the beginning, on certain areas only, at the end when the discussions have already been had and recommendations made. It was also suggested that involvement should be limited to receiving feedback and providing anecdotal evidence as opposed to overall inclusion in the process.

A similar range of views were exhibited over what healthcare conditions participants thought would be suitable for patient contribution to the development of healthcare policies and guidelines, as not all were regarded as being suitable for patient involvement. Despite these caveats patient involvement was thought to be a powerful game changer and a driver for better care. In turn, the patient perspective was noted as being important and a place for patient advocacy was identified.

*"They would actually, they might be able to shift the balance. So if there is a bit of an indecision, they might be able to shift the balance from one side or the other, saying that the effect will have a big effect on their life."* (IA08)

*"The patients should be represented here especially in board meetings and where big decisions are taken. I think it would be good to have patient representative there."* (IA08)

*"They still think em that they are not as competent at interpreting data which in some sense is true but what they do not still comprehend fully is that when we try and involve patients, societies or patient representatives, we are not expecting expert opinion from them as regards interpretation of clinical data, we are expecting the patient perspective."* (IA09)

Participants described the involvement of healthcare professionals with patient societies and working with patients in regards to policy making as positive experiences.

Acknowledgment was made that there are few patient societies in Malta, yet it was developing.

Desire to be involved with patients was verbalised across the multidisciplinary spectrum, albeit to varying degrees. Support was expressed for greater patient involvement with the understanding that the awareness and need for patient involvement is evident and that it is developing. The characteristics of both patients and healthcare professionals were identified as being drivers of this. Responses indicate that for further patient involvement to take place, education is needed not just of patients who need to understand the value and reason for involvement but of healthcare professionals too.

#### **6.3.3.9 Multidisciplinary working**

Echoing the problems associated with stakeholder involvement, which are outlined in the section on facilitation (6.3.5), a lack of cohesive working through either a team or multidisciplinary team were highlighted as preventing implementation of change. It was stated that implementation cannot occur in isolation and therefore without such a coordinated approach, nothing will be effective. Responses indicated that there had been negative experiences in the past when people have not wished to use a guideline, resulting in a conflict between departments and the non-implementation of a guideline. This strengthened the emphasis on the importance of all departments being involved and collaborating. On observations of the guideline group and the focus group, it was evident that participants worked in a multidisciplinary manner. It was observed that reverence existed between professions, with an indication of hierarchy.

Key factors for the success of the implementation of the guidance were depicted as being the people involved (a range of healthcare professionals, managers and policy makers), their attitudes and resources both human and financial. A multidisciplinary focus was seen as crucial as was taking a whole systems approach to implementation ensuring all factors needed for success were in place.

*“There needs to be a responsible person who is going to, who will go remind everyone and audit for the guideline being used or not. I think that is also important and maybe doing face to face meetings and explain what the guideline is all about and a conference about guidelines.” (IB04)*

*“Making sure all the resources are in place, that the whole process, the whole system is in place. I think education of whoever is going to be involved, so that they first of all know*

*about the guideline, know the new skills that they might need to help out in the service.”*  
(IA08)

#### **6.3.3.10 Workload**

It was recognised by respondents that the existing workload, coupled together with a lack of resources of healthcare providers acted as a barrier to the implementation of new innovations. Participants stated that within the hospital, there is a desire to take on new initiatives and a willingness to implement them, but there are not enough healthcare service providers to enable this to happen. The expectation that a new service can be implemented and delivered when the current healthcare service is already under staffed was noted as unrealistic. Participants identified that they and their colleagues can only undertake a workload to a certain point, beyond which there is no more capacity. Participants expressed concern about the amount of service provision that was delivered through the goodwill of healthcare providers, citing that this is not sustainable as it impacts negatively on the individual healthcare provider:

*“So if you had to approach people who are already overloaded with work and ask them to introduce a new service and see even more patients and to do even more overtime, then that won't work. But the general culture I think would be in favour of new services given the resources. I think in general we are all willing to try new things, to be state of the art and so I think in general it would favour.”* (IA08)

#### **6.3.3.11 Communication**

With regard to the role of communication and its importance in facilitating change it was acknowledged as not being optimum amongst departments or even within teams. Functions that should be supportive of communication were stated as not always occurring such as multidisciplinary team meetings. Participants raised questions over how the guidance and recommendations would be implemented if basic systems were not in place.

*“Implementation of things needs to be done with an open communication system, you know.”* (IA04)



#### **6.3.3.12 Service development**

Opinion was that the service needs to be substantially developed in order to support putting the guidance into practice, as the current infrastructure is not suitable. Participants did not think this was a reason to prohibit the development of something new, as there was a drive for change to happen. This was consistent with the understanding that the service has to develop substantially before it will be of the level required in the guidance recommendations. Current provision of service was acknowledged but regarded as unsustainable and in need of development.

Development was seen as possible financially if the government was on board *“Basically if the government here finds it important enough they will finance it... I mean if they really believe in it then it will get implemented.”* (IA03)

The following quote encapsulates this by stating the factors that the service is dependent on; *“the infrastructure, the resources, the manpower, the finances.”* (IA08)

#### **6.3.3.13 Summary**

In this section, there were a number of key novel concepts that evolved, primarily relating to the patient, resources both human and financial and political influence.

Whilst it was determined that the context in which people worked was not always receptive to change and change could often be met with negativity, there was a distinct drive for the implementation of new ways of working and a sense of continuing in what may be regarded as the face of adversity. It was also determined that the receptive context had application to the patient, if they were not receptive to change, then implementation was not possible.

It was further established that healthcare guidelines needed to be created with recognition and sensitivity to context. Guideline development needed to be achieved in a multidisciplinary manner and coordinated accordingly, indicating the need for effective service delivery and cross departmental communication. Patient involvement in healthcare design and delivery was regarded as an area for development as their inclusion was neither systematic nor frequent.

The influence of human and financial resources were seen as key for without it knowledge implementation and change in practice was stated as being impossible. Human resources were an identified restrictive factor, influenced by the small population and restricted options for growth. Financial resources were equally important and reliant on political support. Political influence was another key influential factor be it from the healthcare professional or the patient. Furthermore, the strength of Union representation and their use to challenge changes in practice was another indication of the power of politics within this population.

Analysis exposed culture as being an influential component of the context in which people work, so much so that culture was identified as needing to be a separate standalone section; the multifaceted influence of culture.

#### **6.3.4 Culture – the multifaceted influence of culture**

The topic of culture was distilled from context as it was apparent that its influence and strengths were different to that of context. It will be addressed here looking at the various aspects of culture that were identified illustrating the multifaceted nature of culture.

##### **6.3.4.1 Culture of patient involvement in personal care**

Analysis indicated that there were differing views on whether patients should be involved in their own healthcare and decision making. One line of thought was that patients themselves did not want to be involved as they did not see it was their role to make decisions about their care, take an active role in their healthcare, or in their treatment with some refusing to engage in treatment at all. This reluctance was identified as being due to patients being unwilling to undertake the responsibility of their own care or think they have a role in such decision making. Patients were reported as regarding their healthcare and management of it as being the physician's role. It was stated that an assumption cannot be made that patients want to be involved in decisions about their care.

Patient involvement in their own care was accepted as being influenced by cultural influences. It was however stated that with time, patients will want to be involved in their own care. The following quotes illustrate the interpretation of patient reluctance and emphasises the influence that culture has on personal healthcare management:

*“But as a rule, as a rule, patient think of management as being the responsibility of the doctor primarily and maybe of the healthcare team more generally, but primarily of the doctor. And they are not so keen in being involved in decision making themselves. Even though the guidelines say, would say you have to involve patients, in most circumstances em, most patients would not be too keen to be involved, too keen because they conceive that still as being not their responsibility but the responsibility of the healthcare provider, primary doctor. In fact, if you try to give them options, sometimes they say ‘this doctor really doesn’t know what he is talking about, he can’t decide himself’.” (IA09)*

*“Because they don’t even want to many of them, they don’t even want to know if they suffer from a medical condition.” (IA01)*

*“...You have to change your practice according to the culture where you are practising. Even though in the UK that used to be the norm, here it cannot be the norm. But hopefully it will be because I think that is the way forward because once the patient gets involved in his treatment, I think he also takes more responsibility of his own health (yep, yep). Because there is still that attitude, em my health is not my responsibility, it’s the healthcare gives responsibility (ok). But it will, I mean it will change gradually. Because obviously Malta is not isolated, gets exposed to other cultures. I’m sure it will change, but it takes time”. (IA09)*

A further reason given for the lack of involvement was that some healthcare providers did not think patients should have such a role, indicating the existence of a paternalistic environment, with a sense that patients cannot be given the responsibility of deciding on their care. Patient involvement was identified as not being something that should just be assumed, with one stating;

*“It depends on the patients.” (IA07)*

Participants reported that patients had a lack of health awareness, which was recognised and noted as being something that needs to be changed in society. As a response to this there has been a call for greater public health awareness as public health campaigns have been run in the past to educate populations but they were not seen as having been successful.

#### 6.3.4.2 External influences

Experience of working overseas was reported as having influenced many healthcare providers in Malta, as it was recognised as an education in how healthcare systems can incorporate patients in a number of positive ways such as policy and guideline development and patient centred care. An example given was how, it was good practice to involve patients in the development of guidelines in some UK and European guidelines. In turn, recommendations in these guidelines actively encourage the involvement of patients in their own care. Yet Malta was seen by participants as not being at this stage as patient involvement was identified as still evolving. Specifically participants understood that healthcare providers should drive this change, whilst patients themselves needed to develop an understanding as to why it would be preferable to be involved in their own care.

*"I think that is the way forward and I think eventually with time, patients would want to get involved and there are an increasing number of patient who want to get involved."* (IA09)

#### 6.3.4.3 Work culture

Participants reflected that the organisation within which they worked had a culture that supported evidence based practice. For example, it was noted that there was an integrated use of guidelines; easy access to journal articles, policies and guidelines; encouragement of the use of research and evidence. The existence of the guideline development group within the hospital and their drive for multidisciplinary working was interpreted as an example of the organisations' desire to encourage evidence based practice. The culture of evidence based practice was again attributed to the fact that many healthcare providers had worked or trained in the UK. Participants stated that this experience had instilled in them the habit of working in line with evidence based practice, which was subsequently transposed when they returned to Malta. Despite the presence and knowledge surrounding evidence based practice it was stated that it was still a culture that was embedding.

*"I think there is a growing consensus that this is the way forward and that's it. Certainly I can speak mostly for the medical profession, particularly amongst the upcoming generation. I mean everybody accepts that medicine needs to be practiced in this way."* (IB03)

*"I think that there is a culture within the organisation that would like to move to that, to more evidence base."* (IB09)

Whilst participants reported that there was a culture of multidisciplinary working, this was not something that transcended the whole organisation and was seen as needing further development within the hospital, as elements of separation still existed.

*"We don't even have multidisciplinary team kind of meetings on patient or on strategies."* (IA04)

#### **6.3.4.4 Learning culture**

Enthusiasm towards the organisation exhibiting a learning culture was demonstrated with the appreciation that healthcare professionals are supported to learn within the work environment. Healthcare professionals were seen as having a willingness to learn aided by the fact that the organisation was considered as positively supporting them by actively holding conferences, seminars and other learning experiences. These activities were noted as being multidisciplinary opportunities, benefiting the individual, encouraging cross departmental / health professional working and furthering the service to provide better patient care.

It was reported that healthcare professionals were also given opportunities to learn overseas. Sending healthcare professionals overseas for training was seen as advancing the individual and supporting the learning culture and also benefiting the organisation. It illustrates a recognition of the need for skill development in order to support the healthcare service. This has to occur outside of Malta due to a lack of development opportunities within Malta.

*"We as a medical department, our departmental manager organises yearly medical updates. Yes, and they are really interesting. And the thing works like this. He asks what topics we would like to be discussed, not to be discussed, to be, to have sort of lecturers specialised on that subject...He will organise all these lectures and ..... all the staff, we encourage all the staff to attend"* (FG204)

*"... the training of staff, sending someone abroad on a paid study period to learn the necessary skills and then come back."* (IB02)

#### 6.3.4.5 Society culture

Participants intimated how the culture of the society in which they live influences ones understanding of health and healthcare and linking it to how this is linked to health behaviours. An example given was in relation to weight gain and the reason why for some, it is not perceived as a negative health issue:

*"I think culturally now we know that being obese is not the right thing, we know that it is not so healthy so culturally I think we are now, I remember for example my grandmother who lived post war for her, the fatter you are, the better, it was the culture post war but now I think we've gone. Maybe some elderly patients still think that but the younger ones ... yeh, yeh, they suffered hunger ... in fact when my grandmother tells me 'oooh, you look so good' and then I wait for it 'you have gained weight '!"* (IA07)

The quote indicates how culture influences people's perceptions regarding health and the lifestyle decisions they make which in turn affects their health.

Furthermore, participants recognised that the proximity of both patients and healthcare providers to politicians was a cultural phenomenon and influenced the way in which change within healthcare occurred. This is explored further in the section on politics (6.3.3.7).

#### 6.3.4.6 Summary

In this section it was evident that culture related to a number of distinct factors and therefore could not be regarded as an umbrella term. This resulted in the identification of culture as a separate theme, with a number of subthemes indicating the various ways in which culture impacted on the delivery of healthcare care, implementation of new knowledge and shaped the healthcare organisation. Patient involvement again was key and was divided between patients who did not want involvement in their care and healthcare professionals who did not think that patients were capable of their own care, both being attributed to culture. Culture was further affected by the external influences of working overseas, resulting in healthcare professionals tempering the way in which they worked as the Maltese culture was not yet ready for such patient involvement. Finally the work culture was seen to be positive and supportive of learning and guideline development.

### 6.3.5 Facilitation and the role of implementation

#### 6.3.5.1 Leadership: key opinion leaders

Participants suggested that it was of key importance for there to be clear ownership over whose role it was to both create and implement change (in this case the new guideline). This focused on the inclusion of key opinion leaders as stakeholders both from a medical and policy background. There was an emphasis on the need to make sure that the 'right people' are involved from the beginning of development, who are convinced of the reasons for undertaking the guidance. It was intimated that without this, the guidance would not be successful. Once that involvement should be opened to other departments that need to be aware of the guidelines and ultimately need to use them. Caution was given to the consequences of omitting a key person in the associated field from the development of such a piece of work. This was regarded as having dire consequences to the implementation of the work.

*"I mean the people who are going to implement it obviously have to be on board and take it up." (IA09)*

*"The key opinion leader has to be seen to be in favour of the change and then the others will follow suit." (IA09)*

*"...Its identifying who the top people are, who are the stakeholder that matter who are into this. I think that is the way forward." (IA02)*

*"I think it's a great, great opportunity to unite various stakeholders to set up a cross departmental guideline." (IA02)*

Yet there was an acknowledgement that these 'leaders' alone would not be able to implement guidelines (or other healthcare changes) as they would need support to achieve this on a daily basis. Implementation was therefore characterised as an activity that cannot emulate from one person, as it was recognised as needing to be a multidisciplinary team effort occurring at all levels of responsibility, for it to have the desired impact.

*"... people should work together to implement...the best ideal thing is getting a team of people and their role would be in implementing."(IA04)*

*".. You need a whole team that's going to be working together." (IA06)*

In respect to this guidance, participants clearly identified who they perceived as instrumental leaders in the implementation and acceptance of the guidance. Whilst it was articulated who this should be, there was not such agreement over where the leadership and influence should primarily come from. That is to say, some regarded leadership for change needing to come from medical leadership and others from management, policy makers and hospital leadership.

Suggestions about facilitating the implementation of the guideline included undertaking a feasibility study of the guidance and a skills audit, to ascertain where there may be gaps in regards to the resources (both human and financial) needed for effective implementation and uptake of the recommendations.

#### **6.3.5.2 The role of the individual in the implementation and utilisation of guidelines**

Participants described the role of the individual in terms of being both an enabler and a barrier to the implementation of guidelines and other changes of practice. Management of the individual was referred to as being necessary in some cases to ensure that a positive outcome was reached. Several participants referred to the importance of ensuring particular individuals are involved because of their role and the influence that they can have taking the guidance forwards to implementation. This was an explanation of the influence that individuals can have in the healthcare system.

Participant's perception of their role and how they individually could be involved in taking the guideline forwards was noted as being variable. Some participants clearly regarded themselves as having a part to play in implementing the guidance whilst others were clear that they did not perceive this to be within their remit or ability. At the same time, as identified above in the paragraphs on leadership, the individuals deferred the responsibility for implementation to clinical or managerial hierarchy and decision makers both internal and external to the hospital.

#### **6.3.5.3 Stakeholder involvement**

Some respondents described a lack of stakeholder involvement, representation and ownership as constituting a barrier to the implementation of guidelines, policy or new ways of working. Involvement of what were perceived as being the 'right people' was noted as



being paramount for not only the development of the guidance but its implementation too. This was stated as needing to occur in two ways; not omitting any key stakeholder who would expect to be involved and ensuring that stakeholders who are effective at facilitating cohesiveness of a group and implementation of a guideline are present.

*“I think one of the worst barriers here in Malta is that we are such a small country and em if someone does something, if say I did a guideline for example and I forgot to involve someone important, then I get a major barrier, a major obstruction, probably because we are small and everyone knows each other.” (IA07)*

Reasons for stakeholders not being involved in this particular project included; lack of understanding of the programme, work commitments and not regarding the development of the guidance a priority. However participants said that these reasons were not unique to this project. Participants described the impact that a lack of appropriate stakeholder involvement could have in terms of a refusal to use the guidance and creating the risk of a possible prevention of its introduction.

It was however recognised that appropriate stakeholder involvement throughout the process is a necessity for success. This was seen as being imperative for it was noted that if you do not have the right people then the guidance will not be used. Emphasis was placed on the context in regards to the reason why stakeholder involvement was so important i.e. Malta has a small healthcare provider population and thus it is known who is involved and who is not. The following example outlines the complement of stakeholders that was defined as being needed;

*“I think you would have to get all the stakeholders together from political, public health, medicine, surgery and the allied professionals”. (IA02)*

Participants agreed that the guidance could not be realised in isolation and involvement of other healthcare services and departments was a necessity. Other services to be included were outlined as; primary care, allied health, mental health and other medical and surgical services. Primary care involvement was highlighted as being essential for the implementation of the guidance as an existing strong relationship between primary, secondary and tertiary care was identified. Other than existing relationships, the need for

primary care involvement was because it was stated that this is where the management of obesity and diabetes takes place.

*“I think we should work in conjunction because the bulk of the patients, especially if we are talking about patients with diabetes, the bulk are diagnosed in primary health. So they should be ... these guidelines should be...” (IA06)*

Emphasis was also placed on the need to incorporate decision makers and the health secretary;

*“The most important driver. I think it is local champions, local champions is the... having people who say; I want to run with this despite all the hurdles and obstacles, which are usually first your own stakeholders, the biggest and then the politicians.” (IA02)*

#### **6.3.5.4 Active implementation**

Implementation of the guidance was critical to its success. However, it was felt that this was not always possible as the factors that facilitate implementation are not always adequate to ensure it's uptake. Participants indicated a need for follow up post introduction with actions undertaken such as audit, not only to measure possible success of the guidance but also to ascertain how much it is being used and whether any modifications are needed. A suggestion was made, that the introduction of the guideline should be active rather than passive and thus should be facilitated through educational events such as teaching sessions, question and answer sessions and conferences.

*“Some guidelines need, literally need teaching.” (IB08)*

#### **6.3.5.5 Summary**

Facilitation within this analysis was represented under three key themes of the individual, stakeholder involvement, leadership. The role of the individual was understood as having the potential of being both a positive and negative influencing factor, particularly in regards to the individual as either a leader, facilitator or one that may prevent implementation or progress. Findings indicated that stakeholder involvement was of great importance for without what were termed the 'right' stakeholders being involved, implementation would not be possible. It was also highlighted that this involvement needed to occur from the developmental stage and not just be part of implementation. The role of leadership

indicated the need to have a clear understanding the identification of a key leader, without limiting it to being a medical professional.

### **6.3.6 Section Summary**

This section has identified key themes relating to the three main factors of the PARIHS framework and sub themes within these. The output of the analysis indicates a variation in the strength of these factors, with both evidence and context elucidating more themes than facilitation. Within this, culture was identified as being a multifaceted and strong subset of context, referring to cultural influence that extended outside of the organisation. The analysis further shows the inter-relationship of the three areas.

## **6.4 Experience of developing the guideline.**

### **6.4.1 Introduction**

The development of the guideline took place over two meetings in which the participants were presented with the systematic review evidence of the clinical questions, which they discussed and from which they distilled the recommendations.

This section introduces the findings relating to the participants experience of developing the guideline and focuses.

### **6.4.2 The experience of participation**

Overall positivity was expressed by the participants towards the experience of developing a guideline using this process. This was attributed to working with a clear structure and infrastructure and having the work reviewed and presented by an external organisation. It was noted that undertaking the work externally, alleviated the pressure of completing the work internally as this type of work is normally voluntary and can take a long time to complete. Working with another organisation in this way was also expressed as requiring trust as they had not worked with the organisation before. It was suggested that this may have been easier if more time had been given to develop a relationship between the developers and the guideline group.

*"I think it was quite a very positive experience. I've personally been involved in guideline development previously em ,but without the ,eh, the infrastructure that was afforded to us*

*this time round. So the fact that women who is quite experienced in doing this sort of things on previous occasions and is quite well renowned and good reputation in that regard does the fieldwork in doing the systematic and meta-analysis. I think that was a quite positive experience.” (IA09)*

*“the positive thing is its very interesting and its also a pleasure being part of a group like yours.” (IA04)*

Participants expressed mixed views about the information session that was held during the first meeting. Some participants stated that it was pitched too low and reported that they found it insulting whilst others found it very helpful and informative.

Disappointment and frustration was voiced by participants about the number of people who attended the second session in which the recommendations for the guideline were formulated. Annoyance was expressed that not all group members understood the importance of attending. Participants noted how the lack of attendees affected discussion as those needed for certain aspects were not present and this was perceived as affecting decision making. They questioned whether if there had been a different complement of people, whether the recommendations would have differed. These factors were mitigated by the circulation of recommendations to all involved stakeholders.

*“The good is that something is being done you know.” (IA04)*

Responses indicated that the representation on the guideline group was good, however it was noted that primary care should have been involved.

### **6.4.3 Learning process**

Participants acknowledged that they had acquired a greater understanding of the amount of work required to undertake the systematic reviews. The way in which the work was presented was congratulated, with participants stating that they found it clear and helpful in aiding understanding, principally the visual representation of the results of the systematic reviews. This is particularly important as there was a large volume of information that needed to be understood in a short time period. It was reported that the opportunity to discuss the systematic reviews in a constructive way leading to the formulation of recommendations was helpful and beneficial.

*“When you read is one thing, but when you discuss, it’s another thing and you ask the why, the why, it’s also, you know questions were coming up, but why sort of this. I think it’s the better way.” (IA06)*

Participants explained that they had joined the group with the expectation that they knew what they were going to recommend. Yet, providing the opportunity to discuss the evidence presented resulted in a change in perception and a reassessment of the recommendations, creating recommendations based on the evidence. A sense of pride was exhibited that they had been able to influence the direction of the recommendations and the process undertaken had been successful. Recognition of the active role participants had in data interpretation was made and an acknowledgement that they had derived similar, if not the same interpretations of the data as the guideline group in the UK.

*“We did influence I think because we sort of decided which areas we wanted to look at and then we were involved in the interpretation of the data”. (IA09)*

The analysis revealed that there was no change in the participants views to what evidence based healthcare meant to them. If anything, it consolidated these views but the process resulted in them being more open minded about how evidence could be used and questioned. A process of re-evaluation as to what makes acceptable evidence, was reported by some whilst others identified an improved understanding of research papers.

*“I was surprised about, I mean I knew it but when you actually see so many studies that are poor to maybe moderate, you know when they are all listed one after the other, it really hits home how badly these things are done where weight loss is concerned.” (IA03)*

#### **6.4.4 Summary**

Feedback regarding the experience of developing the guideline was positive overall. Enthusiasm for the project was expressed by all and observed in all situations. A suggestion for this sense of enthusiasm was that this was a key piece of work, being completed by another party. Once consideration of the workload and demands on the individuals and their service, this was of great assistance to them. There was disappointment in regards to the numbers that were present for the last meeting and a sense of a lack of engagement by some stakeholders. To ensure they were kept in the developmental loop, the guideline in draft form was sent to all for comment. This also worked as a way of keeping up the momentum of development and hopefully implementation.

## 7 Chapter Seven - Discussion

### 7.1 Introduction

This chapter presents a discussion of the findings of the study focusing on the key themes that have emerged, linking them to underpinning theory. The chapter discusses each aspect of the PARIHS framework in turn identifying the applicability of the core elements and sub elements cross culturally and noting where further additions to the framework may be made. Other factors identified through the research and development of the clinical guideline will also be discussed. The research questions will be addressed; to explore the appropriateness and utility of a knowledge implementation framework in the cultural translation and adaptation of an evidence based clinical practice guideline, into clinical practice in the healthcare system in Malta; to identify the challenges and barriers to successful cultural translation and implementation to influence future cross cultural knowledge translation programmes.

There are three central elements of the PARIHS framework; evidence, context and facilitation each of which is underpinned by a number of sub-elements (Kitson et al., 1998b). The version of the framework used in this study was that defined in 2008, which detailed the PARIHS framework as a two stage process of evidence and context followed by facilitation (Kitson Alison. L et al., 2008). The following table (Table 7) is a reminder of the sub elements that sit under each component. These sub elements are further expanded within the text surrounding the PARIHS framework to provide further clarity and meaning.

**Table 7: Elements and sub- elements of the PARIHS framework 2008 (Kitson Alison. L et al., 2008)**

EVIDENCE	CONTEXT	FACILITATION
• Research	• Receptive context	• Purpose
• Clinical experience	• Culture	• Role
• Information from the local context	• Leadership	• Skills and attributes
	• Evaluation	

In addition, insight into the process of the development of the clinical guideline and the experience of cross cultural translation and contextualisation will be discussed. Limitations of the study will also be identified and discussed.

This chapter is divided into two main sections ; the PARIHS framework its elements and sub-elements, which includes discussion on the cross cultural applicability of the framework, followed by the guideline development, limitations and barriers.

## **7.2 The PARIHS framework it's elements and sub-elements.**

### **7.2.1 Evidence**

As outlined above, evidence is one of the key components of the PARIHS framework. Within the PARIHS framework evidence is defined as consisting of; research studies (of different kinds), clinical experience, patient's perspective and local contextual information (Sackett et al., 1996, Rycroft-Malone et al., 2002). The findings of this study showed what participants' identified as evidence and how they used it in their daily clinical practice.

#### **7.2.1.1 Interpretation and use of evidence**

The study participants recognised evidence as having a number of aspects, varying from clinical evidence of research trials to clinical experience and / or clinical judgement. The data demonstrated a clear recognition and utilisation of clinical evidence, with it having an identifiable place in the provision of care and a strong belief in its role and importance, resulting in a work ethic that was underpinned by evidence. Although clinical evidence was reported as being the basis on which clinical decisions were often made, an emphasis was placed on what participants regarded as the tangible nature of evidence; that which one could see and feel. This was described as clinical evidence being a form of 'proof' that could be used not just to show that treatment was well guided, but as leverage to make a change to the provision of care. The latter is a reminder not only of the multifaceted nature of the use of evidence but the power that it can have as an instigator for change. For example, a guideline recommendation was made even though it was known the healthcare service was not ready to deliver it. The reasoning behind this was that the guideline is regarded as a form of evidence and therefore as a document can be used to influence those that have the power to fund change (see section 7.2.1.4).

There was a definite sense amongst participants that the use of evidence to underpin clinical practice was an accepted norm amongst healthcare providers and its use was unquestionable. Yet it was also clear that the interpretation of clinical evidence was a skill

and therefore people needed to have the ability to interpret evidence well, in order for it to be applied appropriately. There was however an acute awareness of the vulnerability of research evidence, in particular: the variability in the quality of evidence from clinical trials; the risks of bias; and whether evidence from one population can be applied to another. The importance of using evidence in a particular setting is discussed next.

#### **7.2.1.2 Need for localised data**

There was recognition of the need to have localised data i.e. data that was relevant to the direct population to which it is to be applied. The main reasoning for this is in regards to the available data, as it was recognised as originating from populations of different demographics, economies and healthcare systems thus potentially reducing its applicability. It is this data that is regarded as being fundamental to the contextualisation of guidelines to aid successful implementation (Sharma et al., 2015). It was acknowledged that there is a notable paucity of the existence of local data and the reasons for this were well understood by participants, with reasoning cited as being due to a lack of funding to carry out such studies. Nevertheless, there was an understandable desire for the contextualisation of clinical guidelines and healthcare policy. The type of evidence that constitutes contextualisation is known as ‘colloquial evidence’, which is evidence other than scientific evidence and includes expert opinion and patient views as well as local policy and reports (Lomas et al., 2005). The recognition of the need for local data such as practices and policy, is supportive of the innovation construct as identified in the most latest version of the PARIHS framework, the i-PARIHS (Harvey and Kitson, 2016).

Despite the data demonstrating the drive for contextualisation and local data, this did not extend to patient evidence as data, as it was not regarded by the participants as a key denominator in clinical decision making. This is related to the participants understanding and view of the role of the patient in general and is further discussed in section 7.3.2.

#### **7.2.1.3 Clinical judgement**

However, despite the participants’ inherent understanding of the necessity and uses of clinical evidence, there was a clear and consistent use and reliance on clinical judgement and clinical experience. Clinical judgement was seen as being able to take priority over evidence in some situations, but was generally seen as being used as an adjunct to research based evidence. The importance of using clinical judgement was also interpreted as seeing



patients as individuals, as participants did not want the application of healthcare to be regarded as a 'cook book' i.e. there needs to be tailoring in the application of knowledge. The identification of the individual is also linked to the prior concept of the contextualisation of knowledge and recognition that not all patients are the same. Furthermore the use of clinical judgement was raised as part of the rationale that clinical evidence emulates from specific populations, which may not be relevant to the population which they are treating. The application of clinical judgement and clinical experience was stated as being of further use when there is a lack of clinical evidence. Yet participants noted that a lack of available evidence does not mean that a particular practice is not effective and thus should not necessarily be ignored. In association with the concept of the meaning behind a lack of evidence was the idea of how healthcare professionals, through debate and discussion of their clinical experiences are creating a form of evidence, albeit not in the form of traditional clinical research.

Participants' use of clinical judgement is in line with view that the use of clinical judgement is part of the tacit knowledge that is applied by all healthcare professionals and is the working knowledge on which evidence based practice is applied (Thornton, 2006). The reference to clinical judgement is also in keeping with the PARIHS framework, whereby the use of clinical experience is outlined and cited as being used in conjunction with clinical evidence (Rycroft-Malone, 2010a). Within the framework it is demonstrated that for high to be reached on the continuum, clinical judgement needs to be part of the decision making process, which should be relevant and encompass the views of the relevant healthcare providers (Rycroft-Malone, 2010a). A good example of how clinical experience is used can be seen in the following quote:

*"There is a sort of reassurance that even in the absence of published evidence the discussion is a bit of evidence in itself, also it's a sort of Delphi type of exercise. Yes, the collective evidence of experience rather than 'not, this is how I do it'. I think that's also useful"*

This is an illustration of how evidence from clinical experience is 'tested' by healthcare professionals through discussion with each other, thus making the information more robust which in turn, contextualises the evidence.

#### **7.2.1.4 Clinical guidelines as evidence**

Clinical guidelines were seen as being a useful and acceptable form of evidence and their use was noted as being embedded into practice. They were seen to be a practical and

accessible synthesis of existing evidence. There was an overwhelming acknowledgment of clinical guidelines being used in healthcare practice with participants regarding them as being useful for a variety of reasons; guiding clinical practice, providing an evidence base, supporting decision making, acting as a stimulus for change in clinical practice and service provision , helping to standardise care, reducing conflicting advice.

Participants referred to guidelines as being a useful tool as a lever for sustainable change. By this, they identified guidelines as being used as the evidence to underpin and influence change by presenting them to those with financial control both locally and nationally. In regards to the guideline that was developed during this study, participants were clear that they understood that although the recommendations may not be immediately implemented there was mileage in including them because the guideline would be used to underpin the development of the service and thus they were seen as something to which to aspire. The financial aspect of guideline implementation as mentioned here supports Mala et al (2015) who found that the countries in which successful implementation occurred, were those in which funding for the guideline recommendations to be implemented had been provided (Mala et al., 2015). This not only relates to the concept of using guidelines as evidence to encourage funding but to the latter section on financial resources. This point was identified in practice as after a year of the guidelines being developed, they had been used exactly for this purpose; as evidence to take to the Ministry of Health to initiate discussions around the development and funding of a bariatric service in Malta.

#### **7.2.1.5 Negative guideline use**

There is however a converse to this position as there can be a negative side of the use of guidelines as recognised by participants. The example given and an area noted as concern was that those with financial responsibility may use the lack of inclusion of a treatment into a guideline or the identification of its cost as a reason not to provide it without a real understanding of why it may not be included. This concern was related to a level of scepticism over the use of health economics in guidelines. Some participants indicated their disagreement with decision making being based on economics and questioned whether using evidence in this way is best for patient care. Yet in systems where resources are limited it is difficult to provide everything for everyone in an equitable manner and therefore cost based decisions are made (Eichler et al., 2004). This influence was illustrated by the decision in Malta of the guideline group, who for the recommendation on the use of

pharmaceutical therapy, made the decision that the effect of the pharmacotherapy was not large enough to justify putting it on the government national formulary in Malta, as the cost of providing it to this scale was much greater than the health benefits. They however did not advise against using it if people can independently afford it. The recommendation stated the following: *Recommended not to add Orlistat to the National Formulary.*

#### **7.2.1.6 The use of clinical guidelines**

The ability to access a distillation of clinical research in the form of a guideline was seen by participants as alleviating the workload from already time compressed healthcare professionals as analysis identified that there are competing demands for the implementation of new knowledge. This competition was noted as being due to a number of guidelines being produced at any one time. Thus it is only fair to recognise that this guideline will be implemented alongside other guidelines or aspects of a service. This is in support of the view that because guidelines make evidence more accessible, they work to lessen what is regarded as the gap between research and practice i.e. making research relevant to the clinical practice through guideline interpretation (van der Zijpp et al., 2016). Primarily guidelines were reported as being used for guiding clinical practice either as a support to decision making or to facilitate clinical decisions in an effort to provide the best available care. The utilisation of guidelines as being used to improve patient outcomes through the application of the best available knowledge is regularly cited as the reason for using them (Grove et al., 2015, Francke et al., 2008) allowing for a more standardised approach to healthcare to be applied (Backman et al., 2015). This was identified by participants' that the use of guidelines allows not just for healthcare providers to receive the 'same messages' and thus work in a more coordinated fashion but for patients to also receive standardised care and advice.

#### **7.2.1.7 Access to guidelines**

Participants from both Jordan and Malta reported accessing guidelines from a variety of international sources, such as the World Health Organisation (WHO), international societies and known guideline development organisations such as the National Institute for Health and Care Excellence (NICE). They further identified that the organisations they used were predominately based in the UK, America, Europe and Australia. Whilst respondents regarded guidelines as a positive tool, analysis indicated that they found the plethora of international guidelines challenging, adding to an already demanding workload. This relates

to the complexity of having such an abundance of reference documents which, as participants stated, can cause conflict as there can be contradiction between guidelines in some areas and a lack of guidelines in others. To address this, a number of factors were identified by participants as to how they decide which guideline should be used; availability of resources, patient characteristics, the topic, the most recently developed and by whom it was developed, indicating the multifactorial process of deciding which guideline is most suitable. There appeared to be a process of picking and choosing which guideline best matched the need, rather than which guideline had been developed with the most rigour. Although participants saw the plethora of guidelines as challenging, they did report using them often, aligning with the view of Grimshaw et al 2012 who recognised the usefulness of guidelines as a way to manage the tidal wave of healthcare knowledge (Grimshaw et al., 2012).

#### **7.2.1.8 Trust in and applicability of guidelines**

The analysis showed that participants from both Jordan and Malta used a variety of guidelines but reported that clinical guidelines from well-known sources were used without question as to how they had been developed. It seemed a level of respect and trust was applied to them, without any assessment of the methodology behind the guideline development. The assumption was clearly made that if they were from what were regarded as well reputed organisations, then the methodology must be sound and appropriate. Yet it is well known that there is no international standard of guideline development methodology with variance of quality internationally, particularly if one considers the range of factors that influence a guideline such as; being based on consensus only; the inclusion or exclusion of health economics; the involvement of patients and carers; the scope of the guideline (Qaseem et al., 2012). The Guidelines International Network, with 47 member countries, understands the need for standardisation (Guidelines International Network, 2017). In 2012 they proposed eleven key components to stimulate debate on the development of minimal standards of guideline development (Qaseem et al., 2012). These standards include; the make-up of the guideline development group, documentation of the decision making process, disclosure of conflicts of interest, specification of the scope of the guideline, description of methods used for development, use of systematic evidence reviews, clear evidence based guideline recommendations, a rating system for evidence quality, the need for peer review and stakeholder consultation, expiration date of the guideline, disclosure of any financial support received for the

guideline development (Qaseem et al., 2012). These standards support the process and methods outlined in the NICE guidelines manual (National Institute for Health and Care Excellence, 2017). In regards to the guideline development that was undertaken in this study, the majority of the factors were adhered to, other than disclosure of conflicts of interest and peer review / stakeholder consultation. An expiration date was not set. With hindsight, conflicts of interest could have been recorded for information purposes only.

Paradoxically, whilst there was an overriding acceptance of the standard of guidelines, the applicability and relevance of the recommendations in them were challenged by participants from both countries. Reasons given for this were mainly that recommendations in clinical guidelines developed outside of one's own country can only have partial applicability because of differences in population, availability of medication and resources. These concerns substantiate this research, which looks at the cross cultural applicability of clinical guidelines and the drive for guideline recommendations to be cross culturally translated i.e. the need to make recommendations country specific to ensure applicability, implementation and improved patient outcomes. Whilst these concerns have concrete foundations, there is a risk that suitable recommendations are not used because the default position is that because they are developed in a different context, they are not applicable.

In conjunction with the above, participants identified a number of patient related explanations as to why international guidelines were not always applicable and needed contextualising. Primarily participants stated that the cultural norms of the patient / healthcare provider interactions such as communication, patient participation, level of patient understanding, differed extensively internationally. For example, amongst participants within the context and culture in which they were working it was acceptable to withhold a diagnosis from patients, a 'patient centred' approach did not always apply and the concept knowledge sharing with patients was not necessarily seen as relevant. Recognition of this, which was expressed in both Jordan and Malta not only serves as further reasoning for contextualisation and cultural adaptation, but may provide an explanation for why some challenges are encountered when implementing guidelines from overseas. Participants themselves did not elaborate on their methodology of guideline contextualisation, they just stated that it occurred. Participants noted that they used guideline that they thought answered their clinical questions however they were not explicit as to how they chose which recommendations to use. This is a question that could

have been asked, and greater probing could have been made regarding how recommendations were contextualised. In Malta there was reference to guidelines which emulated from the EU needing less contextualisation than other international guidelines. The need for adaptation of guidelines to make them suitable to their local context is supported by Straus (2013) who also recognises that there are various tools available to guide this process (Straus et al., 2013). One such method is the ADAPTE process which has been designed to contextualise guidelines in other settings (Collaboration, 2009). This is achieved by identifying specific clinical questions and then finding in available guidelines / recommendations that address these questions and are regarded as relevant to the context.

The participants involved in this study provided important insights into the role and limitations of evidence, how evidence is used in practice, what type of evidence is used, the role of guidelines and how it was accepted in the development of the guideline. The element of evidence in the PARIHS framework has overall resonance within this cohort. Yet whilst on the surface evidence as a concept has applicability cross culturally, the analysis and above debate shows that actual application of evidence can only be achieved through contextualisation. What can really be seen is that not all evidence is transferable and that a process of contextualisation is applied to it, whether this is formally or through discussion of healthcare professionals. This suggests that evidence is more socially constructed than may have been previously considered and that it is this social construction that facilitates or prevents the use of evidence in practice whether that is cross culturally or within the same culture or country but in a different context. This again raises the question as to whether recommendations, particularly ones that may be seen as challenging, are not utilised with the excuse being that they are not contextualised. This is a question that may even be addressed on a national scale.

Patient evidence has not been discussed here as it is explored in the section on patients.

### **7.2.2 Context**

The findings of this study support the recently increased focus within implementation science research on the importance of context (Chakkalakal et al., 2013, Sharma et al., 2015). Within the four theories and frameworks originally examined; the Ottawa Model of Research Use (Logan and Graham, 1998), the Stetler Model of Evidence Based Practice (Stetler et al., 2009b), the Knowledge to Action Framework (Graham et al., 2006) and the

PARIHS framework (Kitson et al., 1998b) the role of context is evident yet there is no agreement as to what context is or how it should be determined. According to the definition of the PARIHS framework context is *'the environment or setting in which the proposed change is to be implemented'* (Rycroft-Malone, 2010a)(p118), however there is an absence of clear definition of context (McCormack et al., 2013). Yet a definition for this study is *"the situation within which something exists or happens and that can help explain it"* (Cambridge Dictionary, 2017), as this considers a wider context and not just the immediate context.

The following discussion highlights the influence that context can have on both the development of clinical guidelines and the implementation of knowledge.

#### **7.2.2.1 Recognition of context in guidelines**

Context and the need to recognise it in the development or adaptation of a guideline was a strong theme from this study. In particular, participants identified the importance of patient interaction and how this differs not only from country to country but within different contexts. Thus guideline recommendations that refer to such interactions are often non translatable. This was expanded on by particular reference being made to the assumptions that are made within guideline recommendations for example that communication styles are international, such as shared decision making, which participants did not think applies in all contexts. Participants reflected that within the context in which they worked (both in Jordan and Malta), they often had to adapt their practice to suit the individual patient they were addressing, for example, the data showed that full disclosure regarding medication type and function was not always acceptable and that a more interactive style of consultation was dependant on the patient. This difference in communication styles noted by participants is a strong indication as to why guidelines need to be contextualised, making them not only relevant but acceptable to the user and the patient. This is supported by Brenman et al (2014) who identified that for knowledge to be implemented it is not only healthcare providers that need to agree with a change in practice but the patients too (Brenman et al., 2014). (This is further discussed in section 7.3.2)

In addition, participants highlighted a number of other factors relating to the context of the local setting that should be considered; availability of treatment, drug resistance, care

pathways and patient involvement. There was clear support and understanding of the need for local guideline development and thus support of this study and its associated guideline.

#### **7.2.2.2 The context of society**

The data also demonstrated that context extends beyond the individual department or the hospital and incorporates the context of the wider society and the impact this can have. An example that was distilled from the data was the ease of access that patients have to politicians indicating how patients can influence politicians in regards to the healthcare decisions they make. Consideration of context in this way shows that like culture, it is multi-layered and the influence of context extends beyond the hospital environment in which care is delivered. Consideration of the wider context is thus necessary as it is pivotal in many ways, for example Ekirapa-Kiracho (2014) demonstrated that a model of implementation that may work in sub-Saharan Africa may differ to that which is effective in Europe (Ekirapa-Kiracho et al., 2014), indicating the influence that context can have. Harvey and Kitson (2016), also identify the need for an expansion of context in the i-PARIHS framework (Harvey and Kitson, 2016).

#### **7.2.2.3 Receptive context / non receptive context**

Another aspect of context that emerged was a receptive context, the immediate context in which knowledge is being implemented, and is seen as how ready the context is for change (Kitson et al., 1998b) and the impact this has on implementation. In this study, particular attention was given by participants to the difficulties they had encountered when working in what could be seen as a non-receptive context, for example when either a department or individual healthcare provider was reluctant to change and thus not receptive. Such a lack of receptiveness was not only shown to create reluctance to incorporate change, but created resistance in some circumstances with participants citing healthcare providers seeking trade union support / advice.

The outcome of a positively receptive context was noted by participants who recognised that whilst there is negativity in some contexts, there is also a desire to implement new initiatives. The impact that this receptiveness can have is supported by Yost (2015) who recognised that if the context is of a positive nature then the information or innovation being implemented will be used to a greater extent (Yost et al., 2015). This supports the finding of the importance of harnessing enthusiasm of individuals, which in turn influences



departments and the work context, Bergstrom et al (2012) identifies with this and talks of the overall acknowledgement of the context in which evidence is to be implemented, the important role this plays and how a supportive context is key to implementation (Bergstrom et al., 2012).

Whilst the attitudes and behaviours of individuals and departments were identified as forming a receptive / non receptive context, other factors were also reported such as resources both human and financial, leadership, political influence and the environment. Resources as an influential contextual factor is supported by Bergstrom (2012) (Bergstrom et al., 2012).

Finally, a further type of context that was expressed by participants was the work environment being a context that was supportive of learning and development of all types of healthcare professionals. It was noted that working in such a supportive context, aided not only personal development but patient care, linking context to ongoing professional development. This is a further indication of the role that context has and the need for it to be extended within the framework to incorporate the dynamic and multifaceted nature of context.

It is suggested that the definition of context within the PARIHS framework is modified to take into account the variety of contexts that impact on participants, expanding beyond the immediate environment. A suggested definition for context based on this research is; context is a culmination of the immediate and wider environment / setting in which something occurs.

### **7.2.3 Culture**

The participants involved in this study provided important insights into the role and power of cultural influences. They also illustrated the breadth of culture, its dynamic nature, how it overlaps and how it is intrinsically linked and inter-related to the individual, the patient, context and politics and the symbiotic influence they have on each other. Whilst it is separated out for the purpose of discussion, as a factor, it is not something that should be or can be considered in isolation. As outlined in the literature review culture is multifaceted and is made up of a number of components which occur individually or in conjunction with each other to construct both meaning and action (Swidler, 1986). The visual description of culture being layers, as defined by Geertz (Geertz, 1993) indicates the complexity of culture. Hofstede et al (2010) labelled these layers as; symbols (such as

words and gestures with particular meaning), heroes (those that one models behaviour on or admires), rituals (activities carried out by the collective that may not have any real gain) and values (one behaviour, view, practice over another) and suggested they can be applied to the individual or the group (Hofstede et al., 2010). These aspects defined by Hofstede, plus the suggestions made by Cohen that a person can experience or be a part of more than one culture as culture is tripartite; religion, socioeconomic status and region in a country (Cohen, 2009), are identified by this study.

When examining whether the components of the PARIHS framework are applicable in a culture which significantly differs from the cultural environments in which the framework was developed and primarily tested, it is helpful to review the definition decided on for this study. The definition deferred to in this study is reference to a number of concepts pertaining to culture as opposed to one definition. Therefore, culture is primarily a dynamic state and is a culmination of factors such as values, skills and customs through which meaning and understanding is established (Ryan et al., 2014a) (Swidler, 1986). Importantly a person can belong to more than one culture (Cohen, 2009).

#### **7.2.3.1 Organisational culture**

Within the PARIHS framework culture comes under the element of context and pertains to the organisation, its values and beliefs. It is not about the culture of the individual (healthcare provider or patient) or the wider society culture (Rycroft-Malone, 2010a). The analysis of this study supported the reference to organisational culture as participants referred to the organisational culture in which they worked in terms of the organisation and it being a learning culture. However, the influences of culture within this study extended beyond this and therefore accounted for the meso, micro and macro culture and the inter linkages between them. As it currently stands, the reference in the PARIHS framework to culture accounts for a meso culture but does not take into account the macro culture or the micro culture all which operate by influencing each other and being influenced by each other (Rycroft-Malone et al., 2013). Yet one cannot undermine the importance of an organisational culture that is supportive of the healthcare professionals working within it, implementing and exploring evidence based medicine (Sandström et al., 2015). The culture of an organisation and the sub cultures within that organisation are integral to implementation, with there being a clear difference between cultures that are supportive of the use of evidence based medicine and those that are largely based on tradition (Sandström et al., 2015). The analysis here showed that there was a greater

culture of working within an evidence based framework and drive to achieve this e.g. the development and dissemination of healthcare guidelines. However, there were also aspects of the organisational culture that were more traditional and thus more inflexible when change was being introduced. For example, multidisciplinary working was seen to be in the process of development and still needed to embed as the overall organisational culture. The current organisation was in a stage of development and change with the resultant disparity in organisational culture, leading to the need for recognition that more than one culture can exist within an organisation. McCormack et al (2002) supports this and states that one needs to be aware of this to avoid a cultural collision (McCormack et al., 2002). Such consideration may also be applied to whether the culture within an organisation is an extension of the host culture or is in contrast to it. The following section looks at sociocultural influences.

#### **7.2.3.2 Influence of sociocultural factors**

The data demonstrates the impact and influence of sociocultural factors on the patients' role in healthcare. This was predominately shown in respect to the patients' role in their own care with reference to a lack of patient engagement. Participants recounted that patients often do not regard it as their responsibility to look after their health as this is perceived as being the role and responsibility of the healthcare professional. There was understanding that such behaviour has negative health impacts yet it was noted as being part of the culture. Participants identified that such behaviours were changing but the perception was that it was going to take time whilst the culture changed. This is linked to the disclosure by participants that one cannot make the assumption, that patients want an active role in their care. Chimeddamba et al (2015) identified similar behaviour when reporting on patient beliefs regarding lifestyle modifications and thus active responsibility versus adherence to medication (Chimeddamba et al., 2015). Nor was it thought by some healthcare professionals that patients had the ability to take part in their own care at this level, indicating a clear cultural standpoint of not being patient centred or focusing on shared decision making. Shared decision making has increasingly become a central aspect of UK healthcare, yet this is not to say that all patients wish to take an active role in their care. A study looking at Swedish and English preference towards patient involvement indicated that 66% of the English and 70% of the Swedish participants (total 3125 participants) reported that they did not wish to make healthcare decisions and were content with a less active role (Fredriksson et al., 2017). The authors also stated that this

view was dependant on a number of factors such as culture and setting. What this shows, which is supported by this study, is that an assumption cannot be made that all patients wish for an active role in their care, yet this is a direction that is taken by government and guided by politics.

#### **7.2.3.3 Leadership culture**

It has been established and reported by participants that this study was primarily operating within an environment in which the culture was open to using and implementing evidence based medicine and able to embrace new ways of working. Yet for this to happen, as identified by McCormack (2013), there also needs to be a culture of leadership and support, as this has an overriding impact on the outcome of implementation (McCormack et al., 2013). Data from this study suggested that there is a leadership culture within the departments in the hospital in Malta within which this study took place; these were both internal and external to the Hospital. Whether the culture of leadership is based solely on a hierarchical culture, was hard to determine. However what was apparent was that there was a drive from those in positions of leadership to use their seniority and status to influence and implement change and create a service that has the best possible outcomes for their patients. The culture of leadership was not just evident amongst senior leaders but it was apparent that there was leadership amongst less senior staff and across the healthcare practitioner spectrum as they too clearly identified the need within their departments and how they could be effective in creating and implementing change.

#### **7.2.3.4 Barriers driven by culture**

Consideration, when discussing culture needs to be given to the types of barriers that are driven by culture. Kane et al (2016) during the implementation of World Health Organisation (WHO) mental health guidelines in Uganda encountered a number of barriers and challenges, some of which they attributed to culture; cultural differences between the recommendations of the WHO guidelines and the cultural understanding and beliefs surrounding mental health and the need for cultural adaptation of the proposed interventions (Kane et al., 2016). Without this recognition and contextualisation of the guidelines taking into account the host culture and context, Kane et al (2016) identified that implementation would be challenging (Kane et al., 2016). The same such challenges regarding recognition of culture and the barriers that can be caused by a lack of recognition was indicated in this study, with particular reference to the culture of healthcare delivery

within the hospital, leadership, the patient and the wider political spectrum. The indication from this and that which is supported by Sandstrom et al (2015) is that *“culture cannot be ignored in the attempt to successfully implement guidelines”* (Sandström et al., 2015)(p10).

Cultural influence in the implementation of knowledge as identified in this study has a far greater impact on the organisation, healthcare provider and patient, than the PARIHS framework accounts for. Thus the analysis has suggested that culture as a sub element of PARIHS is under-valued and not receiving attention and consideration to the extent that it should. Currently within the PARIHS framework, culture is a sub element of context but its multifaceted nature which influences so many aspects of implementation such as: learning; hospital environment; society and public involvement, patient engagement in healthcare, is not explored nor are its close links to context. The analysis illustrated that the definition for culture within the PARIHS framework (as with the definition for context) should extend beyond that of organisational culture and encompass the wider social environment whilst also taking into consideration the personal environment and culture. It is therefore proposed that for culture to have real resonance within the PARIHS framework, it should become a separate sub-element. In doing so, it would afford ‘culture’ the consideration needed when implementing knowledge, as awareness of the multifaceted nature of culture, the dynamics this brings and the impact (both positive and negative) can only be productive in the facilitation of knowledge creation and implementation as a greater understanding of an important attribute of context is attained.

#### **7.2.3.5 Context and culture**

Continuing the theme of context and the wider society, the interplay between context and culture became apparent, so much so that the boundaries between the two were blurred at times. For example, this relationship could be seen in both the micro situation of the hospitals and the macro situation of wider society. Clearly one does not exist without the other, with the relationship being interdependent, yet it is not expressed in this way within the PARIHS framework. Within the framework culture is a sub element of context, which on the one hand is a reflection of the symbiotic nature of context and culture but does not help to understand the influences they have independently. To clarify, context is seen as the environment or setting in which something occurs, of which culture is a component (McCormack et al., 2002). Where the PARIHS framework is restrictive is that it only regards context and thus culture from an organisational perspective and does not take into

consideration the wider context / multifaceted nature of culture. The inclusion of culture as a standalone sub element would not only elevate the relevance, influence and place of culture but would also work to explain how both culture and context need consideration and understanding in the implementation of knowledge.

#### **7.2.4 Leadership**

Leadership is a sub element of context within the PARIHS framework. Within the framework it is referred to as a style of leadership that works in a receptive context and a team orientated fashion (Rycroft-Malone, 2010a). Like the area of context, it is also gaining focus as it is widely recognised that the influence of leadership; attitudes, behaviours, approaches and focus, are instrumental to programmes of knowledge implementation (Guerrero et al., 2016). Likewise, there is recognition that leadership not only has an effect on the immediate surroundings e.g. the ward (McCormack et al., 2002) but the wider context of the organisation and that it is something that emulates from both clinical and non-clinical leaders (van der Zijpp et al., 2016). The analysis of this study identified healthcare professional leadership (clinical and non-clinical) within the hospital as having distinctive roles each of which will be discussed.

##### **7.2.4.1 Healthcare professional leadership**

#### **Role 1 - Leadership in the development of knowledge translation and self-perception of leadership**

Participants indicated that they were not clear as to who had leadership responsibility when it came to the development and implementation of a guideline, policy or change innovation i.e they were not sure whether this responsibility was that of hospital management or senior medical leaders. Additionally, not all participants were inclined to identify that they had a leadership role in implementation of this work, preferring to defer to others. The latter may be due to cultural norms, the difference in health professional roles, deeply engrained role division or how individuals perceive themselves on a hierarchical scale of responsibility. The analysis also suggested that participants were keen to identify what were regarded as the 'right leaders', which translated as those who were associated with having 'more power', influence and / or financial resources. This reticence to take an overarching and strategic leadership role in implementation was in contrast to participant's acceptance and willingness to implement the recommendations within their

departments, in a bid to improve patient care. The preference of taking implementation responsibility within individual departments reflects findings by Chimeddamba et al (2015) who documented that healthcare providers were more prepared to take a leadership role to implement guidelines if a team structure was created (Chimeddamba et al., 2015). Perhaps what also needs to be considered is how leadership works in the context/ culture in which it is situated and the influence context and culture have on leadership. This is explored further below.

## **Role 2 - Stakeholders and leadership**

Stakeholders involved in this study were identified as being in a leadership position and/or were seen by others as leaders. Participants suggested the importance of stakeholder involvement in both the development and implementation of a guideline, including healthcare professionals and others responsible for healthcare provision and development. There was a belief that such involvement would help implementation to occur. This corresponds with both Guerrero et al (2016) and Lowson et al (2015) who outlined the importance of involvement of healthcare professionals as stakeholders in the development process of a planned change such as a guideline (Guerrero et al., 2016, Lowson et al., 2015). They state that it not only assists in the understanding of the suggested change, but helps sustain the process of implementation as they are facilitators of change rather than passive receivers. The findings indicated that some of the guideline group were regarded by other members of the group (and regarded themselves) as being key people for successful implementation. Others who were identified as being key to the process of implementation were external to the group but part of the larger healthcare service. Stakeholder leadership was outlined by participants as the importance of having the right stakeholders on board was linked to having the right leaders involved, which in turn was seen as being key to the implementation of evidence into practice. It is interesting to note that as a whole, the guideline group did not see itself as a powerful force for change. The reasons for this are not clear, however it may have been because they did not perceive themselves as a group, as they had only met together twice. It may also be due to the culture of the organisation / society that it is common place to defer to a person of higher status or standing in a situation such as this.

Therefore, reference to leadership in this study was not just in relation to an individual whose role is to lead a group or department, but also of individuals (across the multidisciplinary spectrum) who can lead the implementation of change by example or by

exerting influence over others. This reflects the findings of Yost et al (2015) who concluded that, amongst other variables, the effectiveness of the implementation of evidence into practice is affected by leadership although they could not ascertain what type of leadership was most effective (Yost et al., 2015). Following from this, the data from this study was unclear as to whether it was expected that implementation would be carried out by only those that had taken part in the guideline development group or if it would be expected that somebody else took the role of leading implementation. As a follow up to the study, on revisiting Malta a year after, the researcher was informed that the guideline had been taken by the lead healthcare practitioner of the guideline group and whom the researcher had been liaising with, to the Ministry of Health, indicating that the majority of implementation and follow up had been their responsibility. They may however have taken this action because they were extremely familiar with the guideline, having been involved from the very beginning and thus understood how it fitted fully into the healthcare arena; they were a very senior clinician and therefore had easier access to the Ministry of Health; they perceived it as their role to do this on behalf of the group.

### **Role 3 - Leadership role of the researcher.**

Leadership as a concept was present in the analysis in a range of forms and styles and was seen as something that was both external and internal to the hospital. In this study external leadership was classified as the researcher's role and internal leadership as that of the lead clinician. The lead clinician emerged as they were the person who facilitated the opportunity to carry out the study in Malta. The roles of the lead clinician and the researcher were very clear; the researcher was responsible for directing the group through the process of guideline development from a functional level of coordinating communication and feedback and through guiding discussions regarding the evidence and creation of recommendations and the lead clinician was the driver of the guideline in Malta to ensure delivery of the guideline.

There was a range of views and understandings amongst the group as to how the adaptation of the obesity guideline fitted in with the overall changes that were occurring in the healthcare service in Malta such as the national obesity plan. The researcher clarified the study and the purpose of the guideline to avoid confusion with any other work that may be planned or on going in Malta. Despite these efforts, there was a decision by one healthcare professional not to engage with the process of guideline development. It was not known why they did not want to be involved, but it is possible that lack of



understanding of the purpose of the project or concern over a possible increased workload may have been factors. This lack of engagement did not prevent guideline development or the engagement of others. The guideline group reported that they felt supported, were engaged and positive and noted the importance of the opportunity to focus on the topics identified and develop the guideline.

#### **7.2.4.2 Leadership creating sustainability**

This sense of positivity towards implementation and the feeling of support or provision of support by others in the healthcare system in Malta, is similar to that recognised by Yost et al (2015) who identified that implementation has a greater chance of success if facilitated by leaders who are supportive and regard the implementation in a positive light (Yost et al., 2015). In particular, they identified that in order to make a programme of guideline implementation sustainable, the aspects and actions of leadership needed were; creation of a best practice, positive environment, encouraging and supporting staff to use healthcare guidelines themselves, and having the ability to influence the organisation and the structures within it. It was apparent to the participants in the development of the guideline, that for the translation of evidence to be successful, leadership of the guideline group during development was necessary and this would need to continue following the project end, for successful and sustainable implementation. Having external and internal leadership working closely together as in this study, created a platform for sustainability once the external leadership had been withdrawn. Implementation was the sole responsibility of the internal leader who had successfully used the guideline to highlight the needs of the bariatric service. This is supported by Hauck et al (2013) who identified how the role of leadership plays an important part in the successful translation of evidence and ultimately acts as a driver for change (Hauck et al., 2013). Furthermore, the importance of a secure commitment between the participants of the guideline group in Malta to make implementation sustainable and successful is in support of the findings of Van der Zijpp (van der Zijpp et al., 2016).

In sum, the role of leadership amongst participants was clear, as was the need for a multidisciplinary approach and one that worked from the bottom up as well as the top down. This is something that could be achieved by the range of stakeholders involved in the guideline development group. Whilst leadership is key, it has been suggested that it is important for knowledge implementation to be a part of a programme of sustainable and ongoing quality improvement Bornbaum (Bornbaum et al., 2015).

### **7.2.5 Resources: financial and human**

Resources, both financial and human are acknowledged in the PARIHS framework, as an aspect of culture, which is a sub-element of context. The influence of resources, is based on context primarily in regards to their availability. This section therefore considers the data from the analysis in regards to resources, whilst putting it into context with local data and a consideration of its standing within the PARIHS framework.

#### **7.2.5.1 Financial resources**

Malta is classified as a high income country by the World Bank (The World Bank, 2017b), with 9.7% of Gross Domestic Product (GDP) spent on healthcare annually (The World Bank, 2017a), which translates as approximately \$2471 per capita (World Health Organisation, 2015b). To put this into context, in high income countries, in 2014 the percentage spend of GDP is 12.3% and in the EU 10%, indicating the following table is a comparison of the healthcare spend in Malta, high income countries and the European Union (EU).

The amount spent in Malta has steadily been increasing over the past 30 years (5.7% of GDP in 1995, rising to 9.7% in 2014), although it evidently is not at similar levels as that of comparable EU countries (\$2471 per capita spend compared to \$3613 per capita spend in the EU and \$5251 in other high income countries). However, despite this upward trend in financial resources for healthcare, participants in Malta frequently identified a lack of financial resources as being a barrier to a number of things; the implementation of new innovations; the introduction of new or more healthcare professionals; the introduction of new medications and devices. Financial resources (alongside human resources which will be later discussed) were pinpointed as being one of the most instrumental factors preventing the implementation of the guideline, for it was perceived that if there was not the money to pay for the service recommended and the healthcare professionals needed, then it would not be possible to implement it as the following quote illustrates:

*The guideline on its own is going to be a paper stuck on the wall. We actually need the service, we need the infrastructure, the resources, the manpower, the finances. So the guideline on its own will not change anything."*

Such financial restrictions as illustrated here are not unique to Malta and have been reflected by others who identified limited financial resources as a key barrier to the implementation of guideline recommendations, in terms of supporting change, training,

and purchasing of new equipment (Ellen et al., 2014, Kane et al., 2016, Chakkalakal et al., 2013). Interestingly, these challenges have often been identified in low and low-middle income countries such as Uganda, yet clearly exist in high income countries such as Malta and Canada (Ellen et al., 2014, Kane et al., 2016, Bergstrom et al., 2012).

In conjunction with the data on the restrictions of financial resources, participants in Malta provided important insights into how the availability of financial resources could be influenced, identifying three main channels through which action could be taken to try to secure funding; the Department of Health, direct access to politicians and the Hospital. Furthermore, the ability to exert influence in any of these areas was suggested as being dependant on the individual making the request and relates to the previous section on leadership and the importance of leaders / stakeholder who were regarded as being in a position of influence.

Regardless of the fact that participants of the guideline development group were aware that current funding for the recommendations was limited, it did not prevent them from understanding the utility in creating recommendations for which they do not currently have the resources. The logic behind such thinking was that if such recommendations are included, then it is documentation of the service for which they are striving. Therefore, as previously discussed in the section on evidence, the guideline can be used as a form of evidence to make an approach to the appropriate person or organisation for funding. Whilst it is not the case in this study, a note of caution needs to be paid to the role of 'aspirational' recommendations, as it can have the converse effect and contribute to the disengagement of healthcare providers who may think the recommendations are not relevant to their practice (Straus et al., 2013).

The identification of the restrictions posed by financial resources from low to high income countries, is an indication of the portability of the results of this study and the need for the PARIHS framework to pay greater consideration to the overarching theme of financial resources. As identified, financial resources are also responsible for being able to implement the appropriate human resources (Cometto and Campbell, 2016), a factor which is discussed below.

#### **7.2.5.2 Human resources**

##### **The challenge of a lack of human resources**

Participants reported the challenges of human resources and identified it as being a fundamental barrier to the implementation of change and/or the adoption of a new service or change in healthcare practices. As stated by the World Health Organisation; *“Human resources are the most important of the health system’s inputs. The performance of healthcare systems depends ultimately on the knowledge, skills and motivation of persons responsible for delivering services”* (World Health Organisation, 2000)(p77). This quote supports the premise that without a workforce, with a restricted workforce or one that is not evenly distributed, health systems cannot be effective (Campbell et al., 2013). The data indicated due to the population size of Malta, there is a very small and finite pool of human resources across the health professional spectrum, resulting in some specialties being very under resources as there are just one or two healthcare professionals available.

Participants added that there are not enough healthcare providers to provide the current service, let alone the provision of either additional aspects of healthcare or an entirely new service.

##### **Reasons for lack of workforce**

A number of reasons were identified as to why Malta experiences such a challenge with human resources; the population size impacts on the available number of people to become healthcare professionals; it takes time for people to train and therefore there is no ability for quickly increasing the number of healthcare professionals; once trained there is a percentage of attrition to either the private sector or abroad. These reason are an indication of how contextual factors such as demographics, politics, society and economics, influence the provision of human resources, a notion which is supported by (Squires et al., 2016). Participants stated that action is being taken to try to increase the number of healthcare providers through programs of recruitment to both attract Maltese professionals back from working overseas and to encourage overseas recruitment. Moreover, due to a lack of human resources, Malta relies on physicians from overseas to work for short periods of time in Malta to deliver care in certain specialties (Azzopardi et al., 2014).

### **Workforce complement**

A lack of healthcare professionals, or the wrong complement of professionals is not a situation that is unique to Malta, as it is recognised as a global problem whereby, there is a shortage of healthcare professionals in most countries irrespective of economic standing (Campbell et al., 2013). This makes the implementation of recommendations in such a context a great challenge, and one that needs to be supported through a commitment of politics and policy in conjunction with sufficient financial resources and an investment plan for the introduction of a sustainable workforce (Squires et al., 2016). As mentioned by the Maltese participants and supported by Campbell (2013) and Kane (2016), there is the need for the diversification of existing workforces, which has led the Maltese health sector to look at different ways of delivering care (Campbell et al., 2013, Kane et al., 2016). As mentioned in the data, in Malta there is a move to initiate a care pathways approach to the provision of care to enable better planning and standardisation of the quality of care.

### **Impact of human resource restriction**

The participants were acutely aware of the difficulties caused by a lack of available human resources. They not only identified it as a barrier to implementing innovations such as this guideline, but as restricting departmental improvement resulting in frustration from staff. Participants in both Jordan and Malta reported that it is not just a lack of staff that restricts the introduction of innovations, but as the workload of existing staff is already heavy, they have no capacity to undertake anything else or new, even if the innovation may help to alleviate workload.

The introduction of new services as suggested in the developed guideline would involve upskilling of some, such as in the provision of pre and post bariatric surgery dietary advice, and depending on the numbers referred, an expansion of the workforce would be needed. This echoes the work of Kane et al (2016), who in a study of the implementation of World Health Organisation (WHO) guidelines for mental health in Uganda identified that manpower determined the success of the implementation of the guideline; training for existing staff and procurement of more trained staff across the health professional range (Kane et al., 2016). It is an acknowledgement of how services need to be flexible to respond to healthcare demands and the advantage of a whole systems approach (Scheil-Adlung et al., 2015). This is a crucial aspect of healthcare provision and the need for change and development, which was identified by respondents who stated that there is now

understanding that traditional models of working within healthcare may no longer be a suitable way of providing care. Substantiation of this is well documented in a report entitled Malta; health system review (Azzopardi et al., 2014), which clearly outlines the needs of the Maltese healthcare system to maximise efficiency and make it equitable to all. Developing healthcare guidelines as in this study assists in providing the scope to look at service provision differently as it is looking at country specific service needs by those responsible for providing the service. Overall the data highlighted that in Malta, human resources and the restrictions encountered had a greater reported impact than financial resources. Paradoxically, it was also reported that there have been cases whereby the finances have been available but not the human resources. Whilst in Malta the challenges faced in association with resources focus more on human resources, a change in healthcare practice, or the introduction of a new way of working often requires an investment of both human and financial resources, without which implementing change can become an insurmountable challenge (Ellen et al., 2014).

It is important to note that in regards to the data from the Jordanian focus group, resources, particularly human resources were less problematic. This may be attributed to the fact that the army service is quite well resourced and priorities more defined.

### **7.2.5.3 Resources and the PARIHS framework**

This section has focused on financial and human resources, emphasising how they underpin the implementation of knowledge which aims to change practice, leading to a consideration of where resources fits within the PARIHS framework. The implications of these findings are that the impact of resources in the PARIHS framework, requires greater attention and expansion. Currently, resources is referred to as a sub-component of culture, (which itself is a sub element of context) yet as the above has shown, it is a larger factor than this and whilst being influence by culture, it is also influenced by context and politics. Fundamentally, for healthcare to be effectively provided a suitable workforce and system needs to be resourced (Campbell et al., 2013). Within the PARIHS framework, resources is included under context and within culture, yet on the basis of this study's findings it is suggested that resources is included as a separate sub-element of context, to highlight the impact that resources has on knowledge implementation. The call for this change in status, is supported by Bergstrom et al (2012), who concluded following the assessment of the contextual components of the PARIHS framework in a low income setting, Uganda, that

resources should be a stand-alone sub-element of the PARIHS framework (Bergstrom et al., 2012).

## **7.2.6 Politics**

### **7.2.6.1 Strength of the patient lobby**

The PARIHS framework does not account for the political dimension of evidence use, but the importance of political context emerged as a key finding in this study, with the reported proximity of the Maltese population to politicians being an unexpected theme. The data indicated that the Maltese were able to directly influence politicians, because of easy access to them was referred to as having a profound impact on the way in which changes occurred in healthcare. Such influences were reported as occurring in various forms such as healthcare professionals speaking directly to politicians and patients lobbying politicians as individuals or in some cases in groups. As a strategy, whilst accessing politicians directly seemed to be effective for both patients and healthcare providers alike, the question of equity and fairness was raised by participants as healthcare decisions were not being influenced by evidence but the strength of lobbying. The depiction of this type of action, provided further understanding of the type of role that patients in Malta play in regards to the changes or development of healthcare. This is in contrast to the UK whereby access to politicians is much less direct and therefore such an address is made through patient organisations / groups and in some cases parliamentary groups.

Political influence or utilisation of the power of politics / the political system was also expressed in terms of the use of Trade Unions (a political body that represents the interests of the workers that are its members) by some healthcare professionals in Malta. Such utilisation of the Trade Unions was reported as occurring when healthcare professionals were against a proposed or implemented change. An example given was the standardisation of patient meal times across wards which caused a negative reaction due to an upset of set break times of healthcare providers. Whilst this reaction provides an insight into the behaviour of some Maltese healthcare professionals, it also illustrates the need for understanding the context prior to making a change, in order for there to be less resistance and greater acceptability. Furthermore, it is an indication of the importance of involving appropriate stakeholders which is discussed in the following section.

Politics is not an element or sub-element within the PARIHS framework, although one may argue that it perhaps forms part of a receptive context as structure and system. However, within this section on context, it has been established that the components of context, appear to refer to the immediate context and not the wider context such as political and social structure. Yet the findings of this study reflect the impact and role that the wider culture, greater context and politics can have in relation to the implementation of new healthcare policies and practices. Thus it is suggested that the PARIHS framework is developed to encompass the wider society culture and context, including politics as a sub element of societal context.

### **7.2.7 Stakeholders**

Involvement of what participants regarded as being the 'right stakeholders', from the very beginning of the guideline development was seen as underpinning the success of the guideline development and implementation. Participants explained this even further by pinpointing individual stakeholders who they perceived as being key due to either their social standing, ability to influence or role within the hospital or wider healthcare framework needed within Malta to be able to take the guideline forward to facilitate the final provision needed to provide the service recommended. The influence of the individual is reflected in the addition that was made to the PARIHS framework in 2013 (Rycroft-Malone et al., 2013) whereby the individual is denoted as being key to the process of successful implementation. The importance of stakeholder involvement in particular regard to healthcare providers, has been identified as being instrumental in the implementation and uptake of guidelines (Lowson et al., 2015).

Taking the importance of stakeholder involvement into consideration, a multidisciplinary approach to guideline development was employed to promote implementation. However, despite having identified key stakeholders to be involved, there was a reluctance of some individuals to engage. Reasons for this were unclear as they were not individually articulated. The lack of engagement was verbalised by other group members as perhaps being due to a mixture of factors such as; an absence of understanding of the project; feeling of a threat to a change of practice that had not emulated from within the organisation; feeling that they had not been engaged or consulted with enough; the impact of the researcher who may have been regarded as bringing ideas and views that may not necessarily be welcomed; or a concern that workload would be increased as a result of the



recommendations. The latter is an area that is often referred to in the literature and a reason why knowledge implementation can be a challenge (Ellen et al., 2014).

Due to the above, the final guideline group was not fully representative of all desired healthcare professionals. This was accepted and understood by the other participants of the guideline development group. There was concern from the researchers and some participants, that this occurrence could possibly threaten or undermine the guideline development but this did not ensue. One may say that for some participants the fact that some healthcare professionals were not represented galvanised them into contributing more to the process, perhaps as a form of compensating for others not being there.

To encourage engagement of more reluctant stakeholders, attempts were made by the researcher to make personal contact by email and in person. Group emails continued to include all identified stakeholders leaving open the option if so desired to feedback on recommendations and discussions being left open. What is however important to state is that the researcher displayed awareness of this throughout the process and maintained a position of professionalism and inclusion, giving every opportunity to participate if desired. Yet it must be acknowledged that if someone does not see the utility in being involved, this cannot be forced.

The data indicated the importance of the role of stakeholders and the need to understand the influence they can have. Stakeholder involvement is linked to leadership yet also needs to be considered on its own, as involving all the appropriate multidisciplinary team members will affect uptake across the health sector and moves away from just the influence of one leader. A further issue highlighted in this study, is the difficulties one can encounter when there is a limited human resource, from which stakeholder involvement can be pooled. For if there is resistance or reluctance from a key stakeholder, it is probable that they cannot be replaced by another as they may be the sole person in that role.

#### **7.2.8 Facilitation**

The findings highlighted that participants placed an importance on ownership of the knowledge i.e. the guideline, from the beginning of development through to implementation. This is linked to the above discussion on stakeholders, in particular in reference to who is responsible for the implementation of guidelines or any work based change. They continued by clarifying that whoever this is, it has to be someone with credibility amongst the target audience, thus supporting Grimshaw 2012 who identified

that the choice of facilitator is dependent on the information being implemented (Grimshaw et al., 2012).

Facilitation within this study centred on the facilitation needed to ensure engagement of healthcare professionals, with a keen emphasis on how to work with those that may be sceptical and have the potential to block change. Importance was therefore placed on the need for multidisciplinary involvement and acknowledgement of the risk of there being only one facilitator. In this instance, the lead clinician was primarily responsible for facilitation, although participants understood that they too had a role in implementing the guideline within their clinical departments. There was also recognition that facilitation could occur from outside of the hospital environment through external departments such as public health. As the role of the facilitator is regarded as a supportive role to guide an outcome of changed practice (Harvey et al., 2002), having facilitators from within the hospital and external to it, can be seen as increasing the chances of successful implementation. From this, one can recognise that a facilitator can have different roles e.g. one who wishes to encourage the uptake of a guideline in practice and another who works towards the service funding the recommendations in a guideline. It should be remembered however that the success of both is dependent on a number of variable such as place of work and the individuals involved, thus indicating the inter-relationship of context and culture with facilitation.

### **7.2.9 Summary**

Having now discussed the three main elements of the PARIHS framework, it can be noted that there is a clear interplay between the main elements of the PARIHS framework of evidence, context and facilitation and the sub-elements of implementation and leadership, and thus a need to understand this relationship as identified by Rycroft Malone (Rycroft-Malone et al., 2002). In trying to understand this relationship and seeing how the elements interact with each other brings into questions the conceptualisation of the PARIHS framework as a two stage process of evidence and context followed by facilitation as another (Kitson et al., 2008). This study has shown that these elements are important throughout the duration of the programme of knowledge implementation for the reasons discussed. It is suggested that the framework be acknowledged as one in which there is fluidity as the three main elements gain importance at different times through the life cycle of its use. In addition, there is also interplay between the elements, indicating how one can move between and within the framework. There has been recognition since the revision of

the framework in 2008 by Kitson et al, of the influences that the elements have on one another (Rycroft-Malone et al., 2013), yet there is still a lack of clarity over how it can either be used as either a general 'how to' guide or a framework from which one can pick which elements they intend to incorporate and use.

## **7.3 Barriers**

### **7.3.1 Introduction**

This section explores the need to ascertain and assess barriers, as the evaluation of potential barriers to knowledge translation is integral for the success of the programme (Grimshaw et al., 2012) and should therefore be factored in to a programme of knowledge implementation.

The analysis identified that barriers for implementation included factors such as; stakeholder involvement; workload of healthcare professionals; resources both financial and human; the patient; reluctance of healthcare providers. The indication from the literature is that these barriers are not unique to this study and have been identified in other studies in low, middle and high income settings. The findings from this study support, Chimeddamba et al (2015) in a study looking at the implementation of guidelines in urban Mongolia, noted the following as barriers to implementation; time available to healthcare professionals, increased workload as a result of guideline recommendations and the change in practice, patient preferences, beliefs and health literacy as primary barriers to implementation (Chimeddamba et al., 2015). Similarly they support Murphy et al (2014) who in a study looking at guideline implementation in general practice in Australia, found that having the necessary skills to carry out the recommendations influenced implementation and acted as a barrier, as did time and resources (Murphy et al., 2014). Ellen et al (2014) in a study in Canada, an aspect of which was to look at factors which influence knowledge implementation identified three main barriers; limited resources, time constraints and a negative attitude towards change (Ellen et al., 2014). Finally Straus et al (2013), in Kosovo, looked at determinants of guideline implementation and identified communication as a main barrier, referring to both communication between healthcare providers and clinical groups, plus between healthcare providers and the appropriate ministries (Straus et al., 2013). This shows that the findings from this study about barriers to implementation supports other findings across a diverse range of countries. The importance of identifying these barriers is that by knowing what the barriers are in the

context in which knowledge implementation is to take place, strategies can be adopted to encourage successful knowledge implementation (Ellen et al., 2014).

### **7.3.2 The Patient**

In the UK, the positive contribution of patient and public involvement (PPI) in healthcare research has become increasingly recognised, with the National Institute for Health Research, embedding it into the work that they do in enabling participation (National Institute for Health Research, 2017). There is also a move in the international arena to include patient-based evidence in health technology assessments e.g. guidelines, as a formal type of evidence (Staniszewska and Werko, 2017). With increased involvement has become the need for a more rigorous approach of reporting this, which has led to the publication of international guidance on how to report such involvement in health research (Staniszewska et al., 2017). The guidance, entitled GRIPP2 (short or long form), are checklists written to inform researchers about the areas of PPI involvement that should be reported on to ensure transparency and encourage consistency within research (Staniszewska et al., 2017). Despite this, the role of the patient within the PARIHS framework is not strong, with there being no reference to the patient under either context or facilitation.

Patient evidence is identified as being an acceptable form of evidence, although it is noted as having a different value to clinical evidence (Rycroft-Malone et al., 2002). However in 2013, the role of the individual was added to the PARIHS framework as the role of the individual in the process of knowledge implementation and the influence they can have was acknowledged (Rycroft-Malone et al., 2013). The patient was referred to under this inclusion although the particular influences that a patient can have, was not expanded upon. In 2016, Harvey and Kiston however, added the recipient construct into the i-PARIHS framework, considering how individuals can impact on implementation (Harvey and Kitson, 2016).

Within this study, the theme primarily relating to the patient was a lack of patient engagement in healthy behaviours and self-care; cultural sensitivity; patient engagement with policy and working within the healthcare system and a reluctance towards patient engagement. The following discussion addresses them separately although, it should be noted, that similarity that applies to both is culture, in particular how its influence precludes patient involvement.

### **7.3.2.1 Engagement in healthy behaviours and self-care.**

Data analysis indicated that there were two aspects which related to patients' looking after their own wellbeing; healthy behaviours and responsibility for one's own care. Healthy behaviours were recounted by the participants in Malta as being influenced by sociocultural factors such as; the general influences of a cultural diet which was described as being heavily laden with pastry and pasta; experience of near starvation during the second world war as Malta was intensely bombarded and under sustained attack for the duration of the war, resulting in a food shortage; a lack of exercise and demise of outdoor activity (introduction of computer games, high reliance on cars); overall sedentary lifestyle; and a change in cooking and eating habits from home cooked food to convenience food. These findings reflect the concerns that were outlined in the Healthy Lifestyle Promotion and Care of Non-Communicable Diseases Act in Malta which was introduced in 2016 to promote a lifelong approach to the reduction on non-communicable diseases including diabetes and obesity (Justice Services, 2016).

The second aspect of personal healthcare reported by the participants in Malta was the lack of responsibility that patients took for their own care. There was a noted tendency for patients to rely on health providers to make decisions regarding their care. This would be done without patient influence and is perhaps a window into a paternalistic culture of care delivery. Participants reported that patients regarded shared decision making as a lack of skill on behalf of the healthcare provider in some circumstances, i.e. if the healthcare provider asked the patient for their opinion, the patient regarded this as the consultant not knowing the answer.

Such reluctance to be responsible for one's own health was also identified as a barrier to implementation, for if patients do not see or understand the need for self-care or a change in behaviour, care is more challenging to improve. The involvement of patients in their care can be regarded as slowly developing in Malta with there being some patient groups such as for diabetes and rheumatology as reported by participants. Some of the participants stated that they were active members of the patient group. One may suggest that lack of individual involvement in one's own care may be due to a lack of confidence or understanding of shared care on both sides of provider and patient. Whilst this was not reported as being the case all of the time, as there was apparent variation between participants regarding their involvement of patients. This difference was attributed to the healthcare professionals' view of patient engagement which varied for two reasons: a) the

reason or usefulness of patient involvement was not understood, b) healthcare professionals understood the culture and behaviour of the patient well and altered their behaviour accordingly i.e. they were selective with whom they interacted with in a more patient centred / shared decision making style.

Participants from both Malta and Jordan were clear about the importance of understanding the patient's perspective about health and the patient's views and understanding of health behaviours, for without this, it was acknowledged that conflict can arise between the healthcare provider and the patient. The conflict was noted as being a lack of understanding about the patient. There was however a drive from many of the participants in both countries to ensure that they understood the background (e.g. social, educational) of their patients to ensure they could adapt their delivery of information to an appropriate and suitable manner. A number of participants from both countries reported having practiced for prolonged periods of time overseas where they had worked within environments which focused more on patient partnership and shared decision making, thus indicating a strong knowledge and preferred way of working with patients. Despite having this knowledge, the participants recognised that they needed to be selective in their approach to patients, which was dependant on their understanding of the patient and involved the tailoring of consultation style and approach and the delivery of information. This sensitivity to the individual patient, their culture and context emphasises the importance of knowing the patient and the individual to start the journey towards a more collaborative approach to care. Whilst there was clearly levels of frustration, there was belief that a change in practice would occur, with time being seen as the main facilitator for such change as new ways of patient engagement embedded in the healthcare system (Mercieca et al., 2014).

Surprisingly such sensitivity did not apply across the board as some healthcare professionals regarded patients quite negatively, questioning their ability and intelligence to be able to participate.

#### **7.3.2.2 Cultural sensitivity**

Cultural sensitivity as discussed above, was recognised as being important in regards to understanding patient behaviour and helping to facilitate patient engagement, but also in the application of guidelines from overseas. In both Malta and Jordan, it was reported as being common that guidelines were used from overseas as the resources were not

available to always develop independent guidelines. Lack of cultural sensitivity was particularly explained in terms of the language that is used within some guidelines and the suggestion that patients should be involved within their own care. It was identified, that often the inclusive language of patient involvement is seen as being unacceptable, where the movement for patient involvement and shared decision making is not currently as strong as it is in the UK. The consideration to arise from this data is whether a guideline should be imposed in its original form and thus the expectation to change should be put on the healthcare providers or whether the guidelines should be adapted to incorporate the practice of the host providers. From this study, the data indicated that the guidelines needs to change to take into consideration the context and culture of the host but that also healthcare providers may need to change to be able to implement some recommendations.

#### **7.3.2.3 Patient engagement with policy and working with the healthcare system.**

The second aspect of patient engagement identified in the analysis was patient involvement with policy and the healthcare system. The involvement of patients on guideline development committees did not occur in the development of this guideline (see section below on patient involvement) , yet it was reported by participants that patient participation for the development of healthcare policy emulating from public health development had begun to occur and was slowly increasing. Participants postulated that greater involvement in policy development in Malta may be attributed to it being driven centrally from a government perspective. These findings are supported by a recent report that examined health systems in transition focusing on Malta (Azzopardi et al., 2014) and acknowledges the dearth of patient involvement in healthcare planning, supported this as a policy direction and set out the actions that are or need to be taken in Malta to help address the situation.

The report recognises that: *“There are currently no mechanisms whereby consumers are represented on decision-making bodies in healthcare. However, this is set to change with the enactment of the new Health Act as it provides for the nomination of individuals representing patient associations to sit on the Council of Health. In addition, the new Health Act also sees to the enactment of a Charter for Patient Rights and Responsibilities”* (Azzopardi et al., 2014) (P23). Steps have clearly been taken to increase and improve the involvement of patients, but it is understandable that change is going to take time to occur.

The intention to involve patients in the development of policy, may still be difficult if culturally they are not usually involved in care. The culture of patient groups has begun in Malta as identified and there is positivity that over time the culture will change (Azzopardi et al., 2014). An illustration of this was the positive manner in which some participants spoke of their involvement in specific patient groups, the way in which they regarded the group and their experience as being a part of it.

#### **7.3.2.4 Reluctance towards patient engagement**

The data indicated that patient engagement was an area over which there were diametrically opposed views, ranging from enjoyment of involving patients in their care, working with patients in patient groups, including patients in the development of guidelines and policies to the view that patients should not be involved in the development of guidelines or healthcare policies at all. Participants indicated that patients were not invited to participate as they were not perceived by healthcare providers as having a role or the intellectual capacity to enable them to contribute. At the same time, it was perceived that patients themselves did not see it as their role to take part in this way.

Continuing this theme, there was a level of contradiction amongst participants over the stage at which patients should be involved in the development of work such as guidelines. For example, some participants did not see it as worthwhile to involve for the entire guideline development journey, instead preferred a limited role such as to review guideline recommendations once they had been made. The negative attitude displayed by some participants towards patients and the way in which they were dismissively regarded was unexpected. These views and the reluctance to involve patients may be attributed to an element of fear of working with the unknown or a lack of knowledge about the benefits of working with patients, how to involve them and understanding the extra value they can add in regards to their experiences, views and understanding a topic matter. It was embraced by some for whilst there was a polarisation of views, the general view of involvement was moving more towards being positive and recognition that there was a need to include patients in guideline and policy. Where patient involvement was recounted this was regarded as being fruitful and positive and the input of the experiences of patients and their views respected.



## **7.4 Patient involvement in this study**

This section addresses the level of patient involvement in this study.

### **7.4.1 Recruitment of the guideline development group**

The original plan for the guideline development group included two patient representatives / carers. The model used for the guideline group i.e. the involvement of key stakeholders including patient / carer representatives was based on that which is used by NICE in the UK. For NICE guideline group members, the positions are advertised in the relevant literature and on appropriate websites, calling for participants to apply. Interviews are then held for all members including patients / carers. In situations whereby no application is made and the position remains unfilled, then personal invitations are given. However, this method, did not suit this scenario because the number of key healthcare professionals suitable for this guideline group were limited in Malta. In regards to patients, a system of patient public involvement, such as that which NICE operates, was not available in Malta and takes time to establish. As has been already discussed, patient and public involvement is not at the same level as in the UK and therefore the infrastructure to facilitate such recruitment was not available. Thus the researcher took a different approach and requested for the main clinical contact to suggest two people whom they thought would be suitable and accessible. Two contacts were provided, both of whom were carers. The researcher contacted them and invited them to take part in the group but unfortunately neither were able to attend.

The lack of attendance was discussed with the other guideline group members and the participants gave a variety of feedback as to why they thought the carer did not wish to engage; it was postulated that perhaps those approached did not feel they were suitable; the short notice made it difficult to attend; they may not have fully understood the purpose of the group. For NICE In the UK there is the support of a public and patient involvement unit, which provides support in such situations. This was not available in Malta and thus efforts to recruit patients / careers was not repeated. However, it was apparent through conversation with some participants that if there had been more time, the researcher could have been put in contact with a relevant patient group in order to discuss the guideline development and identify volunteers. In a country where patient involvement is limited, greater time was really needed to gain trust and successful patient involvement. As an outcome of this study, it is therefore recommended that if Malta

wishes to further its patient and public involvement that it considers how it wishes to progress the level of patient involvement and creates not only an infrastructure (through inclusion policies and guidance) that maximises this, but influences the culture to make patient and public involvement a norm.

In summary of this discussion regarding the patient and their involvement in their care and the development of healthcare knowledge, the need for the PARIHS framework to include the role of the patient as an individual element or sub-element is suggested. In doing so, the influence that they have both in the healthcare system and in the development of guidelines such as these can be properly acknowledged. Whilst the framework was originally developed as a tool to assist the implementation of evidence based healthcare (Rycroft-Malone, 2004) as time has progressed and the original elements have become well understood in practice, it would be an opportune time to enhance the patient and their wide reaching role in the development and implementation of evidence based healthcare. It is suggested that the addition of the patient would be similar to that of the individual healthcare professional, which was added in 2013 (Rycroft-Malone et al., 2013, Staniszewska et al., 2013). In doing so, this would be supportive of not only the UK move for greater PPI but the international recognition that PPI involvement needs to be formalised, recognised and reported.

Thus far individual aspects of the PARIHS framework have been discussed in line with the data analysis. Further themes that evolved have also been discussed. This section looks at the functioning of the PARIHS framework and considers whether, following the discussion held, any further alterations to the framework are needed.

The PARIHS framework states that for implementation to be successful all three factors; context, evidence and facilitation need to reach high on a continuum (Rycroft-Malone, 2007). Further work has been undertaken looking at the three components individually (Harvey et al., 2002, McCormack et al., 2002), however it is unclear as to the outcome when two components are overtly strong and are therefore high on the continuum and the other is low. For example in this study, one may say that evidence reached high on the continuum and facilitation was weaker. This work supports work that has been done looking at the relative weight of the elements (Kavanagh et al., 2007) (Bergstrom et al., 2012) and which indicates that the three core elements may not be necessary in all situations. Furthering this reflection of the application of just one or two components of the framework is a consideration of the division of the PARIHS framework in 2008, that

saw the framework divided into evidence + context = facilitation. It is suggested that following the outcomes of this study whereby context and facilitation would affect guideline development and implementation, further consideration needs to be given as to whether the balance of this equation is correct or whether it is needed at all. Finally, a further aspect of the framework that warrants attention is the role of the healthcare professional and the strength of this in terms of context and facilitation. This brings into question culture and whether healthcare provider roles depend on the culture in which they work. Therefore the aspects of context that relate to the individual's role may need to be evaluated in a different manner when one considers the prevailing culture and the influence it has.

## **7.5 Guideline development**

This section addresses the experience and knowledge gained from the development of the guideline as the method of guideline development was also evaluated as part of this study. Insight has thus been gained as to whether the guideline development process itself is also suitable in another country context.

### **7.5.1 Topic identification**

The guideline topic of obesity was chosen by the lead healthcare provider in Malta, who worked closely with the researcher throughout the development of the guideline, through to implementation. It was essential for the guideline topic to be chosen by a Maltese healthcare professional and for the questions to be discussed and agreed upon in Malta. This was because it not only ensured appropriateness and resonance with the wider work programme in Malta and to the context in which it was focused but created a sense of ownership. Without discussion with participants and agreement over the topic of the guideline there may have been less engagement with healthcare professionals. Engagement in this manner and in context, makes the guideline more relevant to the participants and therefore those responsible for implementation, therefore increasing the chances of successful implementation (Rycroft-Malone et al., 2016, Campbell, 2010).

### **7.5.2 Clinical questions**

As the above has shown, it was of great importance to allow for topic choice and direction to emulate from the Maltese healthcare professionals. Therefore following topic

identification of obesity, discussion was had with the lead healthcare professional in regards to the clinical questions that were most pertinent and could be re-reviewed and presented from the guideline 'Obesity; identification, assessment and management of overweight and obesity in children, young people and adults. CG 189. November 2014' (National Institute for Health and Care Excellence, 2014). It transpired that key areas for clinical review in Malta were; the use of pharmaceuticals for weight loss and management and the introduction of bariatric surgery in the obese population and the population with Type 2 Diabetes. Due to the time involved, only the clinical aspects of the questions were to be reviewed and not the health economic aspects, although indicative costs were discussed to help facilitate contextualisation. The actual review questions were;

- a) What is the clinical effectiveness of pharmacological therapy at reducing the weight of people with severe obesity?
- b) What is the clinical effectiveness of bariatric surgery for people with type 2 diabetes who are obese?
- c) What is the clinical effectiveness of bariatric surgery for people who are obese?

For full details of the reviews please see Appendix T.

### **7.5.3 Guideline development and recommendations**

The development of the obesity guideline with the cohort in this study, was based around the interpretation of evidence by the guideline group. Discussions were held about the evidence following which, recommendations were made in the context of Malta.

For the guideline developed as part of this study, contextualisation and cultural adaptation was facilitated by the presentation of evidence to a multidisciplinary group of healthcare professionals in a hospital in Malta. The evidence was discussed by the group and recommendations were formed. These recommendations once written were circulated amongst all participants to ensure as much feedback as possible and thus adequate opportunity to relate the evidence to the context. Participants were predominately presented with the same evidence (albeit updated) as the guideline development group who had written the guideline entitled: *Obesity; identification, assessment and management of overweight and obesity in children, young people and adults (National Institute for Health and Care Excellence, 2014)*. Interestingly, the group in Malta interpreted the data in the same manner as the UK based guideline group. Yet what did however differ were the recommendations as these were made with the Maltese context

in mind. The overall recommendations were similar however three main differences occurred as a result of the interpretation of evidence in context.

Participants expressed gratitude over the development of the guideline and regarded it as a positive activity. Within the hospital there is a guideline development group but they have limited financial and human resources to produce numerous guidelines and development is time consuming. Thus there was an understanding of the time intensity of undertaking systematic reviews and that therefore this guideline slightly reduced that burden. These restrictions were noted as one of the reasons for a reliance on international guidelines and adaptation. However, there was also acknowledgement about the complexity of guidelines which are so complicated that participants felt that adaptation without a contextual review of the literature or the health economic literature would result in a negative alteration. These concerns are supported in a paper by Perez et al 2016 who looked at the fidelity of interventions, in particular how much an intervention has been implemented in the manner in which intended (Pérez et al., 2016). The relevance being that whilst alteration may be seen by those doing the adaptation as positive, it could ultimately impact on the fidelity of the intervention.

Following the presentation of systematic reviews it was discovered that, similar interpretation of the evidence was made by both the guideline development group in Malta as had been made in the UK. Participants who took part in the second meeting were keen to note this and were visibly pleased that such similarities had been reached. Although similar evidence interpretation was made and thus similar recommendations, changes due to context had to be made in regards to the surgical question; there was an increase in BMI ranges in the recommendations from the UK recommendations in the guideline: 'Obesity; identification, assessment and management of overweight and obesity in children, young people and adults'(National Institute for Health and Care Excellence, 2014).

**Table 8: Comparison of UK and Malta recommendations**

<b>Recommendation</b>	<b>UK guideline</b>	<b>Malta guideline</b>
Bariatric surgery for obese people	BMI of 40kg/ m <sup>2</sup> or more	BMI of 45kg/ m <sup>2</sup> or more
Bariatric surgery for obese people with diabetes and /or sleep apnoea	BMI between 35 - 40kg/ m <sup>2</sup>	BMI between 40 - 45kg/ m <sup>2</sup>
Bariatric surgery as an option of choice		BMI of 50kg/ m <sup>2</sup> or more

The reasons for this is due to the fact that the prevalence of obesity is much greater in Malta than it is in the UK, therefore indicating that these differences are a key measure of the needs of the population they are to serve and thus the contextualisation of the data. Malta has been labelled in the European Health Interview Survey (2014) as having the worst overweight and obesity rates in the EU (Eurostat, 2016). A cross sectional study undertaken in Malta between 2014 – 2016 found that 69.75% of the population of Malta was overweight or obese, and recorded an increase in the obese BMI categories and a decrease in the normal and overweight BMI categories (Cuschieri et al., 2016). Therefore given that Malta has a large obese population, the threshold at which bariatric surgery would be performed had to be set higher. By doing this, it was hoped that less strain would be placed on the healthcare service and the chance of the recommendations being implemented would increase.

The same concern regarding the percentage of the population who are obese was employed when considering the evidence for weight loss through pharmacotherapy; the context being that it was not just about whether it should be used but whether it should be added to the national formulary (free provision of a medication by the government). The decision not to add it to the formulary was due to the low effect it had on weight loss and the relative cost implications of making it free for such a large population. The decision making process that underpinned this again illustrated the need for the contextualisation of evidence. See Appendix T for full evidence reports and recommendations.

The formulation of recommendations indicated that the data led participants to make similar recommendations to the UK, but the parameters for intervention changed because of the demographic and prevalence of obesity in Malta, difference in resource availability

and the overall context. Contextualising evidence in this manner is similar to others who have reported the influence of the decision making context on the recommendations being made (Dobrow et al., 2006). This analysis suggests the need to develop a system for situational interpretation of evidence that is robust and accessible and is supportive of the use of the PARIHS framework to adapt a clinical practice guideline, for example, consideration of the following; how evidence is discussed in context; facilitation of discussion; consideration of elements and sub elements of PARIHS and how these elements are used to guide the interpretation. In addition to being supportive of the PARIHS framework as a means of evidence translation and adaptation it also acts as an illustration of the symbiotic nature of two elements of the PARIHS framework; evidence and context and how evidence is considered within the context in which it is presented. Interpretation of evidence on this basis cannot be separated from the context in which it is being interpreted and thus this research supports the notion that the PARIHS framework should not be divided and should remain a fluid process. In addition to the contextualisation of the evidence, it is interesting to note that the language used to write the recommendations was changed from the original NICE recommendations. This was because there was concern that the meaning of the recommendation would be lost if the language did not suit the Maltese environment. This echoes the writing of Zoreda 1997 who identified the close relationship of language and culture again indicating the importance of the influence of context and culture on the guideline.

At the same time this research demonstrated that the overall methodology used for guideline development e.g. working as a guideline development group, engaging with the group from question formulation to finalisation of recommendations, is transferable and can be replicated in another country.

#### **7.5.4 Challenges encountered in guideline development**

Some participants commented on the fact that at the beginning of the process it was not clear to them how the guideline work linked to other programmes of work in Malta concerning obesity. As it transpired that sending such information by email had not been effective, time was taken at the first meeting to clarify how the work would fit in to the overall work programme.

An initial training session was held with the group as an introduction to the process of guideline development. Reaction to this session was mixed with some participants

reporting that the level was too basic and others indicating that it was at the right level. This difference may be due to experience of the healthcare professionals in critical appraisal and systematic reviews. It illustrates the challenge of working with a group of healthcare professionals whose exposure to the development of healthcare guidelines differed.

There was a lack of transferability in the way in which guideline recommendations are written in the UK as the initial form of words used, which was based on the original guideline was altered. Initially the recommendations were written using the same form of wording as is used in NICE guidelines, however feedback was clear that this was not appropriate for the Maltese context because the intention of the recommendations would not be understood. The recommendations were subsequently changed with input from the Maltese healthcare professionals to make them acceptable to the audience from whom they were intended.

## **7.6 Rigour / trustworthiness within this study**

The intention of rigour / trustworthiness within a study is to demonstrate validity of the data with an emphasis on the importance of honest and accurate representation (Holloway, 2005). It is important at this juncture to revisit this and understand how trustworthiness has been addressed in this study. The five components of trustworthiness as outlined by Holloway and Galvin (Holloway and Galvin, 2017) were upheld in this study.

1. Dependability – the method of data collection has been clearly outlined and recorded, thus providing an audit trail if another researcher wanted to undertake the same process of data collection and analysis. See chapters four and five.
2. Credibility – participants involved with the development of the guideline were given a number of opportunities to feed into the design, development and recommendations of the guideline. Participant insights and views were considered and included.
3. Transferability – the transferability of this study has been discussed throughout the discussion by relating aspects of the study in line with the international literature. In doing so, relevance to a similar context has been discussed.
4. Confirmability - the objectives of this study, as outlined at the beginning of the chapter have been achieved through the research. There is a clear audit trail to allow for the data gathered to be tracked.



5. Authenticity – the researcher has worked to ensure that the views of participants have been reported fairly by reporting quotes verbatim and ensuring confidentiality. Furthermore, original work was an outcome of the study.

## **7.7 Limitations**

This section outlines limitations encountered whilst undertaking this study and how they were addressed.

### **7.7.1 Language**

As noted, all the research was carried out in English. In retrospect, for the Jordanian focus group, it may have been preferable to have had the option to participate in Arabic. Whilst the group were excellent at conveying their responses, there were some participants who were much quieter than others, which may have been because of language. It is not possible to discern whether this was attributed to other factors such as rank, mixed male / female cohort, mixed health professions or ranking of profession or army. Whether more data could have been obtained if it has been held (or the option given) in Arabic, is unknown. Furthermore, it is challenging to conduct such an intense meeting in a second language, and being aware not to over simplify or create leading questions through simplification. Language did not cause the same concern in Malta.

### **7.7.2 Time**

The timescale in which the project was run was commented on by the participants in Malta as being a limitation of the study. Due to the study having to be relocated to Malta part way through the PhD, it meant that the time available for the project was condensed. This meant that lead in time whereby the researcher would have had the opportunity to spend time with the participants of the guideline development group on an individual basis, to introduce the project, gain confidence from them in what was being undertaken and provide an idea of how the guideline development fitted with the bigger picture of tackling obesity in Malta was not possible. This would have been helpful as it would have afforded the researcher the opportunity to prepare for; facilitation of or help with the inclusion of those who were more reluctant to join in; plan for working with the group overall; and allow each participant to feel more involved with the process. Yet, although time was

reduced, the negative effects of which have been commented on, the majority of participants were extremely efficient at understanding the concept and engaging fully.

The impact on time also resulted in a reduction of the number of clinical questions to be addressed. Although this was not the preferred approach, this did mean that the questions chosen were focused on areas of most need, pertinent to the problems faced and where attention had not yet been focused. The result was a concise, short guideline regarded by participants as having the potential to improve the provision of care. The guideline was shortened from a full guideline of 16 questions, to just three clinical questions, to ensure the work would be completed whilst maintain the integrity of the work and ensuring the questions were addressed to the full and usual standard applied to the development of a guideline.

The timescale had a further impact with participants as the overall planning for the guideline group was affected. The guideline development group set up was modelled on the NICE guideline development groups whereby recruitment for the guideline group participants is through an application and interview process in the first instance and invite if places are not filled, was altered to invite only. The Hospital is the main tertiary hospital in Malta and all participants were identified as necessary stakeholders, Preference would have been to action a more transparent and open system of recruitment. The reasons being that there is more transparency regarding the selection process and all those interested have a chance to express their interest. Advertising also allows all to know it is happening, thus raising awareness and helping to ensure that all specialties are covered. Time has been previously noted as impacting on the involvement of patients. Consideration has been given as to whether adequate lead in time, would have resulted in more suitable approaches to any interested patients or carers and engaging with willing patients in an appropriate way.

The final impact of time restriction was the inability to observe the implementation of the guideline. This would have added the opportunity to observe the cross cultural use of the guidelines. Whilst observation of the process was not possible, follow up was made as the researcher was invited to Malta a year after the initial development to present the guideline to a wider audience and took the opportunity to learn more about the implementation of the guideline. At this point, the guideline had been presented to the Ministry of Health as a starting point to develop the service needed to support the implementation of the guideline.

Due to the timescale of the guideline development and overall study, the researcher did not have time to engage with people on a one to one basis and therefore have the extended time to make sure all stakeholders were identified and willing to take part. Verbal feedback suggested that those who did not wish to engage may have felt less threatened if such contact had been made as they would have had more time to understand the project outline and intention and have more opportunity to raise any concerns or ask questions prior to commencement.

### **7.7.3 Substitution**

As the population of healthcare professionals in Malta is small and under pressure from the service, it was suggested by participants that the guideline group members, should have had the opportunity to be substituted by others. This is something for future contemplation however, this would not have been applicable in all departments in the Maltese case scenario, as some departments did not have any other healthcare professionals with whom to substitute. Greater co-ordination between healthcare professional may also have allowed for attendance to have been better and representative across the board. To compensate for attendance levels and optimising opportunity, the meeting papers, notes, presentations and recommendations were circulated amongst all members for comment and feedback, so that all had opportunity to contribute.

## 8 Chapter Eight - Conclusion and recommendations

### 8.1 Overview

This study was carried out using a case study methodology and the methods of; focus groups, semi structured interviews and observations. The research aims, which have been met were;

- 1 To explore the appropriateness and utility of the PARIHS framework, in the cultural translation and adaptation of an evidence based clinical practice guideline into clinical practice in the healthcare system in Malta<sup>4</sup>.
- 2 To identify the challenges and barriers to successful cultural translation and implementation to inform future cross cultural knowledge translation programmes.

In order to do this, a short clinical guideline was developed and thus the guideline development method was also evaluated as part of the study to establish whether it is a suitable method in another country context. Guideline development and the formulation of recommendations were addressed through the decisions of a multidisciplinary group of Maltese healthcare professionals using the NICE methodology of guideline development (National Institute for Health and Care Excellence, 2017) . Analysis was performed using framework analysis.

### 8.2 Key findings

Chapters six and seven, covering the findings and the discussion have addressed each element of the PARIHS framework in turn, plus findings in addition to those related to the PARIHS framework. The key findings from this study are:

- **Evidence;** There was an affirmation of the importance of clinical evidence in decision making and practice, with a call for the need for more localised data, to increase the applicability of the evidence. An understanding of the use and role of clinical judgement was identified. There was recognition of clinical guidelines being a form of evidence in themselves. Which factors influenced decision making on which guidelines should be used was noted, bringing in the importance of applicability to context and

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<sup>4</sup> This study began with the Royal Jordanian Medical Services, however due to unforeseen circumstances the study site had to be changed to Malta. See Chapter 2 for further explanation and background.

culture. The element of evidence in the PARIHS framework resonated with the participants.

- **Context;** There was an indication of the influence context can have on both the development and implementation of clinical guidelines / knowledge. Context was identified as being wider ranging than the immediate context and the importance of acknowledging societal context was documented.
- **Culture;** Culture stood out as being a powerful and important influence and having greater complexity than is suggested by the PARIHS framework. The breadth of culture, its dynamic nature, how it overlaps and how it is intrinsically linked and inter-related to the individual, the patient, context and politics and the symbiotic influence they have on each other was illustrated. Areas of particular focus were; organisational culture and its varied dimensions, leadership culture and barriers driven by culture
- **Leadership;** The role of leadership was identified with in a number of ways; roles pertaining to healthcare professional leadership; leadership in the development of knowledge translation; participants' self-perception of leadership;; stakeholders and their role in leadership; the leadership role of the researcher and the lead clinician; the effect of leadership on the sustainability of implementation. .
- **Resources;** The findings in this study referred to both financial and human resources and their relative influences. Financial resources were viewed in regards to the impact a lack of resources can have, whilst human resources were recognised as a factor that could undermine the implementation of change or the adoption of a new practice. The impact of a lack of human resources was inextricably linked to context. Both illustrated the portability of the results of this study to other countries whereby resources have a negative impact on the implementation of new ways of working, thus bringing into question the transferability of NICE guidance.
- **Politics;** The importance of political context (both national and local) was a key finding in this study, in particular the proximity of the Maltese population (service providers and patients) to politicians, which was understood as having a direct impact on the development of healthcare provision.
- **Stakeholders;** There was a perception that stakeholders needed to be what was termed as the 'right people' i.e those with the ability to facilitate the implementation of the guideline or at least, set it on the right path to implementation. Participants understood that it was their responsibility to either implement the guideline or orchestrate its implementation. Additionally, stakeholder participation was influenced

by limited human resources, another indication of how context (and components of it) interlink.

- **Facilitation;** Participants identified facilitation as the need to ensure the engagement of multidisciplinary healthcare professionals from the beginning of guideline development.

Through such engagement it was felt that all would be empowered to facilitate the implementation of the guideline. It was also noted that a sole facilitator was a risk as there was clear understanding that implementation was a team effort occurring at different levels of the organisation.

The study showed how the PARIHS framework is applicable and relevant to a programme of guideline development and knowledge implementation. However, it identified that the elements should be acknowledged as being fluid and reconsideration of the concept of the PARIHS framework as a two stage process of evidence and context followed by facilitation should be made. This is because the three main elements are relevant at different times through the project and there is interplay between the elements, indicating how one can move between and within the framework.

- **Barriers;** Key barriers to implementation were identified as; stakeholder involvement; workload of healthcare professionals; time available to healthcare professionals; resources both financial and human; the patient, their healthcare beliefs and understanding of care; reluctance of healthcare providers to engage with change.
- **The patient;** the role of the patient was prominent, influential and identified as multi-dimensional including the following; the influence of socio-cultural factors on patient involvement; the impact of the patient's perspectives / understanding about health; provider sensitivity to the individual patient's culture and context; slow emergence of patient engagement; the reluctance towards patient engagement emulating from healthcare professionals, who also felt patients would be reluctant to engage.
- **Guideline development;** As an aspect of the identification of the barriers to successful knowledge translation, the method of guideline development was evaluated to establish whether it was a barrier or facilitator in the Maltese context. Therefore, it was important that guideline topic identification and clinical questions development were made by a Maltese clinician, helping to ensure relevancy to local need. The guideline development process was acknowledged as being appropriate thus suggesting that the overall methodology of guideline development is transferable and can be replicated

internationally. Formulation of recommendations were contextualised, as participants had a clear understanding not only of healthcare demographics, context and culture but of how to target and focus the language of recommendations to achieve successful implementation.

## **8.3 Identification of original contribution to knowledge**

### **8.3.1 The impact of this work on the PARIHS framework**

One of the main outcomes of this research are empirically based findings about how the PARIHS framework can be improved.

- Enhanced inclusion of culture in the PARIHS framework. *Culture* currently exists as a sub-element of *context* within the PARIHS framework. In 2002 the need to understand the divergent cultures that are present in an organisational context for change to be enduring were documented (Rycroft-Malone et al., 2002). Yet, the framework does not define what culture actually is, nor does it consider the influence and impact of culture beyond the organisation as has been identified here. Therefore, it is suggested that for culture to be truly a part of the framework, it needs to be regarded on a macro, micro and meso level, for its influences are applied on all these levels. Additionally, the definition of culture should be wider reaching and encompass the social environment as well as the personal environment and culture.
- Define what context means within the framework. Like culture, there needs to be an acknowledgement that it should go beyond the organisation i.e. the context in which the organisation exists. In addition a receptive context does not just relate to the professional but also to patients.
- The individual was introduced into the framework but not the role of the patient. The patient has such an instrumental and influential role that they should have greater prominence and be a part of the framework either as a sub-element of the individual or a stand-alone element.
- The role of politics can have a strong influence. Whilst it is not strong enough to be an individual element it should be a sub element of context for awareness of it is needed as it is a factor that can be manipulated creating very different outcomes.

- If the main elements of the PARIHS framework are being considered as single units, then acknowledgment of the fact that one element may have greater strength in a situation than another needs attention.
- Resources both human and financial have a larger impact than the framework credits. Both aspects of resources should be prominent under context, and should be considered as a clear sub-element, as they can be the main barrier to implementation.
- This study may be regarded as contributing to the evidence base of the i-PARIHS framework (Harvey and Kitson, 2016) particularly the constructs of; context, innovation and recipient.

### **8.3.2 Contextualisation of guideline development**

The understanding that evidence is only part of the story of guideline development. The influence of the culture and context in which the interpretation of the evidence can have a profound effect on the final recommendations. The culture and context was extended to the use of language as the language traditionally used by NICE was recognised as not being appropriate for this audience. Thus recommendations need to be written in a manner that has cultural resonance with the audience.

## **8.4 Recommendations for policy and practice.**

- The PARIHS framework is used for the implementation of knowledge in a variety of settings but would be strengthened by the additions outlined in this conclusion to ensure that it has cross cultural and contextual applicability. By doing so, the framework's relevance will be enhanced both in the UK and internationally.
- Practitioners and policy makers developing and/or implementing guidelines need to consider the multifaceted nature of culture and the influence it has on a spectrum of factors; the organisation, the healthcare professional, the patient, society, relationships such as that with politicians.
- Practitioners and policy makers need to take into account that the use of guideline recommendations are not only dependant on the evidence but the context in which they are developed. In turn this highlights the need for such sensitivity when implementing knowledge cross culturally.
- Practitioners and policy makers need to recognise the spectrum of how patients can exert influence on the provision of healthcare and/or decision making. Additionally, greater understanding needs to be given to the reasons why patients are willing or



reluctant to engage in either their care or other involvement, to ensure effective patient engagement.

- Acknowledgment that human resources as well as financial resources are influential in the use of guidelines. If this is ignored, implementation of change may not be achievable.
- Implementation to be made part of any policy / guideline development, considering it from the outset. Understanding of barriers up front may assist in reducing barriers to implementation. This is where the PARIHS framework can be utilised, as it allows for the consideration of the three main elements and sub elements in design, development and implementation. Encouragement should thus be made that the PARIHS framework be used as a developmental guide.

## **8.5 Recommendations for research**

1. Establish whether contextual and cultural influences effect the formulation of guideline recommendations in the UK. For example, by presenting the same evidence to two guideline development groups in different parts of the UK and then examining the recommendations from the two groups.
2. Additional research is needed on the individual influence of the elements of the PARIHS framework and how each element may be used individually and how they interact with each other.
3. Define whether the PARIHS framework really is a two stage process or a fluid process whereby the elements can work independently, in parallel and movement can be multi-directional.
4. Once the areas of addition that have been identified have been incorporated into the PARIHS framework, further research will be needed to understand and evaluate their impact.

## **8.6 Conclusion**

It can be concluded that the PARIHS framework can be used to guide the cultural translation and adaptation of an evidence-based clinical practice guideline in a cross-cultural setting. Yet, this should be better achieved if the factors identified from the analysis are incorporated into the framework. The study has highlighted the multidimensional nature of culture, the influence of context, the interplay between the two and the often under-estimated role of the patient, politics and human resources.

## 9 Chapter Nine - References

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## 10 Chapter Ten - Appendices

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24<sup>th</sup> October 2014

PRIVATE

Miss Elizabeth Avital  
38 Wroxham Gardens  
London  
N11 2BA

**Appendix A – BSREC Approval 1**

Dear Miss Avital,

**Study Title and BSREC Reference:** *An exploration of the appropriateness and utility of a knowledge implementation framework in a cross cultural context*, REGO-2014-1269

---

Thank you for submitting your revisions to the above-named project to the University of Warwick's Biomedical and Scientific Research Ethics Sub-Committee for approval.

I am pleased to confirm that approval is granted and your study may commence.

Please keep a copy of the signed version of this letter with your study documentation.

Yours sincerely



David Davies  
Chair  
Biomedical and Scientific  
Research Ethics Sub-Committee

**Biomedical and Scientific  
Research Ethics Sub-Committee**  
A010 Medical School Building  
Warwick Medical School,  
Coventry, CV4 7AL.  
Tel: 02476-151875  
Email: [BSREC@Warwick.ac.uk](mailto:BSREC@Warwick.ac.uk)

Medical School Building  
The University of Warwick  
Coventry CV4 7AL United Kingdom  
Tel: +44 (0)24 7657 4880  
Fax: +44 (0)24 7652 8375



17/08/15

PRIVATE

<b>Appendix B – BSREC Approval 2</b>
--------------------------------------

Dear Elizabeth

Study Title and BSREC Reference: [An exploration of the appropriateness and utility of a knowledge implementation framework in a cross cultural context](#)  
[REGO-2014-1269 AM01](#)

---

Thank you for submitting a substantial amendment application for the above-named project to the University of Warwick's Biomedical and Scientific Research Ethics Sub-Committee.

I am pleased to confirm that the changes that you wish to make to this study have been approved.

Please keep a copy of the signed version of this letter with your study documentation.

Yours sincerely

pp

A handwritten signature in black ink, appearing to read 'Scott Weich', with a stylized flourish at the end.

Professor Scott Weich  
Chair  
Biomedical and Scientific  
Research Ethics Sub-Committee

**Biomedical and Scientific  
Research Ethics Sub-Committee**

A010 Medical School Building  
Warwick Medical School,  
Coventry, CV4 7AL.  
Tel: 02476-528207

Email: [BSREC@warwick.ac.uk](mailto:BSREC@warwick.ac.uk)

## Appendix C – Ethics approval Jordan

G. H. Q. Jordan Armed Forces  
DIRECTORATE  
ROYAL MEDICAL SERVICES  
Director of Professional Training  
and Human Resources Development  
Amman – Jordan

بسم الله الرحمن الرحيم

الهيئة العامة للقوات المسلحة الأردنية - الجيش العربي  
مديرية الخدمات الطبية الملكية  
مديرية التأهيل الطبي وتنمية القوى البشرية  
عمان - الأردن

١٩٥٥

الرقم : ت ف ١/٣/الخلاقيات المهنة  
التاريخ : جمادى الآخرة ١٤٣٦  
٢٩ آذار ٢٠١٥

السادة شركة LIZ AVITAL  
الموضوع : الدراسات

تحية طبية وبعد.....

• أوصت لجنة البحوث والدراسات السريرية والدوائية وأخلاقيات المهنة باجتماعها رقم ( ٢ / ٢٠١٥ )  
والذي عقد يوم الاثنين الموافق ٢٠١٥/٣/١٦ بالموافقة على اجراء الدراسات التالية بعنوان :

- National clinical guideline/ royal college of physicians

واقبلوا الاحترام....

ع/ اللواء الطبيب  
مدير عام الخدمات الطبية الملكية

الوالس  
مؤسس اتحاد الأطباء

نسخة الى :

- مدينة الحسين الطبية
- مدير التأهيل الطبي وتنمية القوى البشرية
- مدير مكتب عطفة المدير العام
- سكرتير لجنة اخلاقيات المهنة

ROYAL MEDICAL SERVICES  
Professional Training Division  
Amman - Jordan



١٩٥٧

الرقم : ت ١٢ / ١ / ٢ / ٢  
التاريخ : جمادى الآخرة ١٤٣٦  
أذار ٢٠١٥

### المادة Royal college of physicians

الموضوع : الدراسات

تحية طبية وبعد.....

- أوصت لجنة البحوث والدراسات السريرية والدوائية وأخلاقيات المهنة باجتماعها رقم ( ٢ / ٢٠١٥ ) والذي عقد يوم الاثنين الموافق ٢٠١٥/٣/١٦ بالموافقة على اجراء الدراسات التالية بعنوان :

- Quality improvement in healthcare, establishing an evidence and economics base to underpin decision making.

- National clinical guideline/ royal college of physicians

واقبلوا الاحترام....

ع/ اللواء الطبيب  
مدير عام الخدمات الطبية الملكية

الراسل  
مؤسس معهد التدريب



نسخه الى :

- مدينة الحسين الطبية
- مدير التأهيل الفني وتنمية القوى البشرية
- مدير مكتب عطوفة المدير العام
- سكرتير لجنة اخلاقيات المهنة
- التداول

## Appendix D - Faculty of Medicine and Surgery Malta, full ethics approval

L-UNIVERSITÀ TA' MALTA  
Msida - Malta  
KUMITAT TA' L-UNIVERSITÀ  
GHALL-ETIKA FIR-RIĊERKA



UNIVERSITY OF MALTA  
Msida - Malta  
UNIVERSITY RESEARCH  
ETHICS COMMITTEE

20<sup>th</sup> January 2016

Ms Liz Avital  
Liz.Avital@rcplondon.ac.uk

Dear Ms Avital,

**Re: An Exploration of the Appropriateness and Utility of a Knowledge Implementation Framework in a Cross Cultural Contrast**

As Chairperson of the University Research Ethics Committee, I am pleased to inform you that UREC has approved your research proposal entitled: "**An Exploration of the Appropriateness and Utility of a Knowledge Implementation Framework in a Cross Cultural Contrast**".

Yours sincerely,

pp

Professor H Grech  
Chairperson

University Research Ethics Committee

UNIVERSITY RESEARCH  
ETHICS COMMITTEE

## Appendix E - Focus group questions Jordan

<b>Jordan Focus Group questions</b>	
<b>Section 1: What is evidence?</b>	
1.	Can you tell me what you understand by the word evidence? (evidence is information from relevant valid sources) <ul style="list-style-type: none"> <li>a. How would you define it?</li> <li>b. What does it mean to you?</li> <li>c. What do you use?</li> </ul>
2.	Does the term evidence based healthcare / evidence based practice mean anything to you? <ul style="list-style-type: none"> <li>a. How would you describe it?</li> </ul>
<b>Section 2: What underpins practice (What helps you in your healthcare practice?)</b>	
1.	How do you decide what to do in health care practice? <ul style="list-style-type: none"> <li>a. What is it based on; clinical knowledge (through experience or study), economics, patient based, evidence (from relevant sources), peer views?</li> <li>b. Think about what you base your practice one.</li> </ul>
2.	How do people develop their knowledge? <ul style="list-style-type: none"> <li>a. What do you do to learn new things?</li> <li>b. What do you think your friends / colleagues do?</li> <li>c. Is it just through formal education ...</li> <li>d. How do people change their practice – what informs that?</li> </ul>
3.	In Jordan, do you have any examples of what evidence is used to inform healthcare practice? <ul style="list-style-type: none"> <li>a. How do you decide what to do?</li> <li>b. Can you describe what sort of evidence is used and where it is from</li> </ul>
<b>Section 3: How is evidence / knowledge used in health care settings</b>	
1.	Can you tell me how you use evidence in the health care setting/s you work in? <ul style="list-style-type: none"> <li>a. Can you give me some examples?</li> <li>b. Do you think other people would have the same view?</li> <li>c. What term do you use for evidence?</li> <li>d. What is difficult about using evidence?</li> <li>e. Do you think about how you practice in comparison to others?</li> </ul>
2.	Do you use health care guidelines? ( <i>a document, based on evidence, to help you make decisions about the best treatment of care to give</i> ) <ul style="list-style-type: none"> <li>a. What do you think of guidelines?</li> <li>b. Do the guidelines you use come from Jordan or from overseas? <i>Where would you say they mainly come from?</i></li> <li>c. When they are from overseas do you need to change them?</li> <li>d. Are you allowed to change them?</li> <li>e. Would others people use them in the same way?</li> </ul>
3.	If you are using new evidence, who finds the evidence? <ul style="list-style-type: none"> <li>a. Does it come from the hospital, university, somewhere else or do you have to find it?</li> <li>b. How are people told about it?</li> <li>c. Email, meetings, conversation?</li> </ul>
4.	Who is responsible for putting evidence into practice? <ul style="list-style-type: none"> <li>a. How is this currently done?</li> <li>b. Who actually does it?</li> <li>c. Does it get done?</li> <li>d. Would colleagues in other hospitals say it is put into practice in the same way?</li> <li>e. How does it help you?</li> </ul>
5.	What are the barriers to putting evidence into practice <ul style="list-style-type: none"> <li>a. What helps to get over these barriers?</li> </ul>



- b. Do you think there are barriers for different professional organisations e.g. is it different for nurses to physicians?
- 6. When you change practice, what happens i.e. what is the process, who tells you?
  - a. How do you change?
  - b. How does it happen?

## **Appendix F - Focus group invitation letter Jordan (participant information leaflet)**

*Study Title: Developing and using guidelines in practice*

*Researcher name: Liz Avital*

This PhD study focuses on developing our understanding of a knowledge implementation framework called the Promoting Action on Research Implementation in Health Services (PARIHS) framework, and its suitability for adapting and using healthcare guidelines in Jordan.

This study is part of a larger programme of knowledge implementation being undertaken by the Royal College of Physicians London by the National Clinical Guideline Centre (NCGC). The NCGC is commissioned by the National Institute for Health and Care Excellence (NICE), to produce evidence based clinical practice guidelines, which aim to improve the quality of patient care within the NHS in England and Wales.

The study is for a PhD being undertaken by Liz Avital, supervised by Prof Kate Seers and Dr Sophie Staniszewska. The study is supervised by Warwick Medical School.

### **Focus group**

A focus group is an opportunity to have a group discussion about a topic. The purpose of this focus group is to understand how evidence based health care is used in practice in Jordan. By participating, you will be contributing to that understanding. The focus group will consist of 8 – 12 people.

### **Participation**

You are being invited to participate in this study because you are healthcare professionals working in Jordan. You are free to decide if you wish to participate. If you agree to participate, you will be asked to attend a focus group, in English, on xxx day at xxx time in xxx room. The focus group discussion will last for about an hour. In order to hold the focus group the meeting will need to be recorded. A colleague will be writing notes throughout the focus group session.

Your participation in the focus group is entirely voluntary. If you decide to participate you are free to withdraw at any time before or during the focus group. Should you decide to withdraw, if you wish, any data collected about you will not be used and will be deleted.

### **Confidentiality**

The recordings and notes of the focus group will be kept confidential. They will not be shared with anyone else including work colleagues. Your name does not need to be recorded, however recording your profession would be useful, if you agree. All recordings, notes, will be stored in encrypted and secured files for ten years after which they will be disposed of according to the University of Warwick procedures.

## **Use of data**

When the focus groups are completed, the recordings and notes of the focus groups will be written down and used to understand how knowledge translation is perceived in the Jordanian context and what current knowledge translation practice is. From this, the information gathered will also be used to help inform the questions for the semi structured interviews to be held prior to guideline development. A final report will be written which will be provided to the RMS.

## **Contact details**

Please ask any questions you may have now. If you do have any questions later, you can email them to me at [Liz.Avital@rcplondon.ac.uk](mailto:Liz.Avital@rcplondon.ac.uk)

The contact details of my supervisors are:

Professor Kate Seers  
Director RCN Research Institute  
Division of Health Sciences  
Warwick Medical School  
University of Warwick  
Coventry CV4 7AL  
[kate.seers@warwick.ac.uk](mailto:kate.seers@warwick.ac.uk)

Dr Sophie Staniszewska  
RCN Research Institute  
Division of Health Sciences  
Warwick Medical School  
University of Warwick  
Coventry CV4 7AL  
[sophie.staniszewska@warwick.ac.uk](mailto:sophie.staniszewska@warwick.ac.uk)

## **What if there is a problem?**

This study is covered by the University of Warwick's insurance and indemnity cover. If you have an issue, please contact Jo Horsburgh (details below).

## **Who should I contact if I wish to make a complaint?**

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a Senior University of Warwick official entirely independent of this study:

Jo Horsburgh  
Deputy Registrar  
Deputy Registrar's Office  
University of Warwick  
Coventry, UK, CV4 8UW.  
T: +00 44 (0) 2476 522 713 E: [J.Horsburgh@warwick.ac.uk](mailto:J.Horsburgh@warwick.ac.uk)

## **Who has reviewed the study?**

This study has been reviewed and given favourable opinion by the University of Warwick's Biomedical and Scientific Research Ethics Committee (BSREC): **REGO-2014-1269**

**Funding**

This study is funded by the Royal College of Physicians London

*Thank you for taking the time to read this participant information leaflet*

## **Appendix G - Letter to RMS informing them of the project and requesting approval.**

Dear Sir

We are undertaking a study as part of a larger programme of knowledge implementation being undertaken by the Royal College of Physicians London, by the National Clinical Guideline Centre (NCGC). The NCGC is commissioned by the National Institute for Health and Care Excellence (NICE), to produce evidence based clinical practice guidelines, which aim to improve the quality of patient care within the NHS in England and Wales. The RCP is currently establishing a program of evidence translation and utilisation in international healthcare systems that wish to standardise their use of guidelines.

The objectives are to:

- 1) Look at whether the Promoting Action on Research Implementation in Health Services (PARIHS) framework (a knowledge implementation framework) is suitable for use in adapting healthcare guidelines in Jordan.
- 2) Identify challenges and barriers to successful adaptation and putting guidelines into practice to inform future knowledge translation programs.

We would like to undertake the research within your organisation. The research will be carried out using a case study approach, with the use of qualitative methods to underpin the approach: a focus group, semi-structured interviews, non-participant observation and recorded patient outcome data. The PARIHS framework will be used to guide the development of an evidence based clinical guideline in Jordan, based on an existing NICE guideline. Development of the guideline will take place through a series of meetings in which the clinical evidence will be reviewed and from which a guideline will be developed.

Research activities will occur in the following order: focus group, pre-guideline development semi structured interview, development of guideline, post-guideline development semi structured interview, guideline implementation activity.

The dissemination of the guideline will be the responsibility of the RMS.

The study is supervised by Warwick Medical School.

For further information, please contact Liz Avital, [Liz.Avital@rcplondon.ac.uk](mailto:Liz.Avital@rcplondon.ac.uk)

Yours sincerely

Ian Bullock

COO National Clinical Guideline Centre

## Appendix H - Focus group statement of consent Jordan

**Title of project:** Developing and using guidelines in practice

**Name of researcher:** Liz Avital

Please circle yes / no to the following statements (you will be given a copy of this form)

I confirm that I have read and understood the information sheet for the above study	Yes / No
I agree to take part in the focus group	Yes / No
I agree that the discussion may be audio recorded	Yes / No
I understand that any information I provide is confidential	Yes / No
I understand that my participation is voluntary and that I am free to withdraw from the discussion / withdraw from the study at any stage without giving any reason	Yes / No
I understand that anonymised quotations may be used in publications resulting from this research	Yes / No
I agree to take part in the above study	Yes / No

Name of the participant:

Signature:

Date:

Name of the researcher:

Signature:

Date:

## **Appendix I - Focus group questions Malta**

### **Introduction**

#### **What underpins practice**

- Can you describe what sort of things inform health care practice?
  - What is it based on; information, evidence, peer views ?
- How do people develop their knowledge?
- In Malta, what evidence is used to currently inform healthcare practice?
  - Can you describe what sort of evidence and where it is from

#### **What is evidence?**

- Can you tell me what you understand by the term evidence?
- What does the term evidence based healthcare mean to you?

#### **How is evidence / knowledge used in health care settings**

- Can you tell me how you use evidence in health care setting?
  - Do you think other people would have the same view?
- Do you use guidelines? (define guidelines)
  - Do you adapt them to suit your setting?
- Who finds the evidence and how are people told about it?
- Who is responsible for putting evidence into practice.
  - How is this currently done?
  - Who actually does it?

## **Appendix J - Email invitation to focus group Malta**

Dear

I would like to invite you to take part in a focus group discussion on *Tuesday 19<sup>th</sup> January, from 11 – 12.30pm* at the Mater Dei Hospital (room to be confirmed). The aim of the focus group is to explore how evidence based health care is used in Malta and is an informative part of a PhD I am undertaking focusing on knowledge implementation. The attached document explains the study and the focus group in more detail.

Please can you respond as to whether you can attend, by *Friday 8<sup>th</sup> January 2016*.

Professor Stephen Fava, who is supporting me to carry out my PhD in Malta, kindly passed me your contact details.

I look forward to hearing from you.

Kind regards and season's greetings

Liz Avital



## **Appendix K - Focus group invitation letter Malta**

### **Focus group invitation (participant information leaflet)**

*Study Title: Developing and using guidelines in practice*

*Researcher name: Liz Avital*

This PhD study focuses on developing our understanding of a knowledge implementation framework called the Promoting Action on Research Implementation in Health Services (PARIHS) framework, and its suitability for adapting and using healthcare guidelines in Malta.

This study is part of a larger programme of knowledge implementation being undertaken by the Royal College of Physicians London by the National Clinical Guideline Centre (NCGC). The NCGC is commissioned by the National Institute for Health and Care Excellence (NICE), to produce evidence based clinical practice guidelines, which aim to improve the quality of patient care within the NHS in England and Wales.

The study is for a PhD being undertaken by Liz Avital, supervised by Prof Kate Seers and Dr Sophie Staniszewska. The study is supervised by Warwick Medical School.

### **Focus group**

A focus group is an opportunity to have a group discussion about a topic. The purpose of this focus group is to understand how evidence based health care is used in practice in Malta. By participating, you will be contributing to that understanding. The focus group will consist of 8 – 12 people.

### **Participation**

You are being invited to participate in this study because you are healthcare professionals working in Malta. You are free to decide if you wish to participate. If you agree to participate, you will be asked to attend a focus group, in English, on XXXXX day at XXXX time in XXXX room. The focus group discussion will last for about an hour. In order to hold the focus group the meeting will need to be recorded. A colleague will be writing notes throughout the focus group session.

Your participation in the focus group is entirely voluntary. If you decide to participate you are free to withdraw at any time before or during the focus group. Should you decide to withdraw, if you wish, any data collected about you will not be used and will be deleted.

### **Confidentiality**

The recordings and notes of the focus group will be kept confidential. They will not be shared with anyone else including work colleagues. Your name does not need to be recorded, however recording your profession would be useful, if you agree. All recordings, notes, will be stored in encrypted and secured files for ten years after which they will be disposed of according to the University of Warwick procedures.

## **Use of data**

When the focus groups are completed, the recordings and notes of the focus groups will be written down and used to understand how knowledge translation is perceived in the Maltese context and what current knowledge translation practice is. From this, the information gathered will also be used to help inform the questions for the semi structured interviews to be held prior to guideline development. A final report will be written which will be provided to the RMS.

## **Contact details**

Please ask any questions you may have now. If you do have any questions later, you can email them to me at [Liz.Avital@rcplondon.ac.uk](mailto:Liz.Avital@rcplondon.ac.uk)

The contact details of my supervisors are:

Professor Kate Seers  
Director RCN Research Institute  
Division of Health Sciences  
Warwick Medical School  
University of Warwick  
Coventry CV4 7AL  
[kate.seers@warwick.ac.uk](mailto:kate.seers@warwick.ac.uk)

Dr Sophie Staniszewska  
RCN Research Institute  
Division of Health Sciences  
Warwick Medical School  
University of Warwick  
Coventry CV4 7AL  
[sophie.staniszewska@warwick.ac.uk](mailto:sophie.staniszewska@warwick.ac.uk)

## **What if there is a problem?**

This study is covered by the University of Warwick's insurance and indemnity cover. If you have an issue, please contact Jo Horsburgh (details below).

## **Who should I contact if I wish to make a complaint?**

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a Senior University of Warwick official entirely independent of this study:

Jo Horsburgh  
Deputy Registrar  
Deputy Registrar's Office  
University of Warwick  
Coventry, UK, CV4 8UW.  
T: +00 44 (0) 2476 522 713 E: [J.Horsburgh@warwick.ac.uk](mailto:J.Horsburgh@warwick.ac.uk)

## **Who has reviewed the study?**

This study has been reviewed and given favourable opinion by the University of Warwick's Biomedical and Scientific Research Ethics Committee (BSREC): **REGO-2014-1269 17<sup>th</sup>**

**August 2015**

**Funding** This study is funded by the Royal College of Physicians London

*Thank you for taking the time to read this participant information leaflet*

## Appendix L - Focus group consent form Malta



**WARWICK**  
MEDICAL SCHOOL

**Focus Group Statement of Consent**

**Title of project: Developing and Using Guidelines in Practice**

**Name of researcher: Liz Avital**

Please read the following and sign your agreement to participate below. You will be given a copy of this form for your information.

I confirm that I have read and understood the information sheet for the above study  
I agree to take part in the focus group  
I agree that the discussion may be audio recorded

I understand that any information I provide is confidential  
I understand that my participation is voluntary and that I am free to withdraw from the discussion / withdraw from the study at any stage without giving any reason  
I understand that anonymised quotations may be used in publications resulting from this research  
I agree to take part in the above study

**Name of participant:**

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Researcher: Liz Avital**

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Contact details: [Liz.Avital@rcplondon.ac.uk](mailto:Liz.Avital@rcplondon.ac.uk)

**Researcher's supervisors:** Professor Seers and Dr Staniszewska

Signature:  Date: 14/1/16

Contact details: [Kate.Seers@warwick.ac.uk](mailto:Kate.Seers@warwick.ac.uk) and [Sophie.Staniszewska@warwick.ac.uk](mailto:Sophie.Staniszewska@warwick.ac.uk)

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## Appendix M - Email introduction to the guideline development group

Dear Guideline Development Member

As you are aware, you have been selected to be an expert member of a multidisciplinary guideline development group (GDG) to develop evidence based recommendations for the management of obesity in Malta. You are tasked with working through the clinical evidence presented, to make clinical recommendations by committee that are relevant to the local context.

The guideline will be developed over a series of meetings:

1. **Friday 22<sup>nd</sup> January 11-2pm at the Mater Dei Hospital** (room to be confirmed) A meeting to look at the methodology of guideline development, review of the existing guideline and recommendations, protocols and review questions, GRADE and critical appraisal, interpreting/ understanding health economic evidence in guideline development.

This meeting is run by Dr Kate Kelley, methodological expert from the UK and forms the basis of the guideline development.

2. **Thursday 25<sup>th</sup> and Friday 26<sup>th</sup> February at Mater Dei Hospital (time and room to be confirmed).** Review of the clinical evidence which will be presented by a research expert from the UK, from which the committee will create recommendations suitable to the Maltese context. This will be chaired by myself and Professor Fava.

***Please confirm your attendance at the meeting to be held on Friday 22<sup>nd</sup> January by Wednesday 13th January.***

Attached is further information about the research that this guideline development is a part of. Please do email me if you would like more information or have any questions.

I look forward to working with you.

Kind regards

Liz Avital

**Liz Avital | Senior Operations Manager, India**

**International Department | Royal College of Physicians**

**11 St Andrews Place | Regent's Park | London NW1 4LE**

**Direct line +44 (0)20 3075 1345 | Mobile 07903836984 | Fax +44 (0)20 7486 4034**

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## **Appendix N - Outline of guideline development, international adaptation.**

The development of the guideline is part of a larger programme of knowledge implementation being undertaken by the Royal College of Physicians London, by the National Clinical Guideline Centre (NCGC). The NCGC is commissioned by the National Institute for Health and Care Excellence (NICE), to produce evidence based clinical practice guidelines, which aim to improve the quality of patient care within the NHS in England and Wales. The RCP is currently establishing a program of evidence translation and utilisation in international healthcare systems that wish to standardise their use of guidelines.

The objectives are to:

- 1) Look at whether the Promoting Action on Research Implementation in Health Services (PARIHS) framework (a knowledge implementation framework) is suitable for use in adapting healthcare guidelines in Malta.
- 2) Identify challenges and barriers to successful adaptation and putting guidelines into practice to inform future knowledge translation programs.

The research is being carried out using a case study approach, with the use of qualitative methods to underpin the approach: a focus group, semi-structured interviews and non-participant observation. The PARIHS framework will be used to guide the development of the evidence based clinical guideline in Malta, based on an existing NICE guideline. Development of the guideline will take place through a series of meetings in which the clinical evidence will be reviewed and from which a guideline will be developed.

Research activities will occur in the following order: focus group, pre-guideline development semi structured interview, development of guideline, post-guideline development semi structured interview, guideline implementation activity.

The dissemination of the guideline will be the responsibility of the Mater Dei Hospital.

The study is supervised by Warwick Medical School, UK.

For further information, please contact Liz Avital, [Liz.Avital@rcplondon.ac.uk](mailto:Liz.Avital@rcplondon.ac.uk)

## Appendix O - Email invitation to the pre and post guideline development interview

Dear

I would like to introduce myself. I am Liz Avital, the researcher running the guideline development project, to which you have been invited. Through this project we will develop a guideline recommendations specific to the needs of Malta. The guideline development is also part of a PhD entitled “Developing and using guidelines in practice”.

As part of the PhD I will be holding semi structured interviews with members of the group prior to and following guideline development. I would like to interview you before the guideline development to gather an understanding of how you regard guideline development, and what your thoughts are about the use of clinical guidelines, and after to see how you found the process of development. The attached document explains further about the interviews.

The interview will last for up to an hour and will be at the Mater Dei Hospital. **Please select 2 or 3 times** for an interview schedule to be arranged.

<b>Tues 19 Jan</b>	14:00	15:00	16:00	17:00	18:00	19:00

<b>Weds 20 Jan</b>	08:00	10:00	10:00	11:00	12:00	13:00	14:00	15:00	16:00	17:00	18:00	19:00
<b>Thurs 21 Jan</b>												

To allow time for all interviews to be confirmed, please can you respond by *Thursday 14th January 2016*.

I look forward to working with you

Kind regards

Liz

**Liz Avital | Senior Operations Manager, India**

**International Department | Royal College of Physicians**

**11 St Andrews Place | Regent's Park | London NW1 4LE**

**Direct line +44 (0)20 3075 1345 | Mobile 07903836984 | Fax +44 (0)20 7486 4034**

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## **Appendix P - Pre and post guideline development interview information**

*Study Title: Developing and using guidelines in practice*

*Researcher name: Liz Avital*

This PhD is part of a larger programme of knowledge implementation being undertaken by the Royal College of Physicians London by the National Clinical Guideline Centre (NCGC). The NCGC is commissioned by the National Institute for Health and Care Excellence (NICE), to produce evidence based clinical practice guidelines, which aim to improve the quality of patient care within the NHS in England and Wales.

The study is for a PhD being undertaken by Liz Avital, supervised by Professor Kate Seers and Dr Sophie Staniszewska. The study is supervised by Warwick Medical School, UK.

### **Semi structured interviews**

I would like to undertake semi structured interviews with members of the guideline development group prior to commencement of guideline development (and following development of the guideline). I would like to interview you before the guideline development to develop an understanding of how you see guideline development, and what your thoughts are about the use of clinical guidelines. I would like to interview the same people, about three months later, after the completion of the guideline either face to face, on the telephone or on Skype.

### **Participation**

If you agree to participate, I will be holding the interviews on **Tuesday 19<sup>th</sup>, Wednesday 20<sup>th</sup> and Thursday 21<sup>st</sup> January 2016** at the Mater Dei hospital. The interview will last for up to an hour. For accurate data collection the session will be recorded using an audio-digital recorder. If you do not wish for an audio-digital recorder to be used, I will only write notes.

Your participation in the interview is entirely voluntary. If you decide to participate you are free to withdraw at any time before or during the interview. Should you decide to withdraw, if you wish, any data collected about you will not be used and will be deleted. By taking part in the interviews you will be helping to see whether the guideline development process affects people's views about evidence based healthcare and clinical guidelines.

### **Confidentiality**

The recordings and notes of the interview will be kept confidential. They will not be shared with anyone else including work colleagues. Your name does not need to be recorded for the purpose of the interviews, however it is normal practice for GDG members' names to be published in the guideline. Data will therefore be stored in encrypted and secured files for ten years after which they will be disposed of according to the University of Warwick procedures. A report will be published at the end of the study.

### **Contact details**

If you have any questions please email me at [Liz.Avital@rcplondon.ac.uk](mailto:Liz.Avital@rcplondon.ac.uk)

The contact details of my supervisors are:  
Professor Kate Seers



Director RCN Research Institute  
Division of Health Sciences  
Warwick Medical School  
University of Warwick  
Coventry CV4 7AL  
[kate.seers@warwick.ac.uk](mailto:kate.seers@warwick.ac.uk)

Dr Sophie Staniszewska  
RCN Research Institute  
Division of Health Sciences  
Warwick Medical School  
University of Warwick  
Coventry CV4 7AL  
[sophie.staniszewska@warwick.ac.uk](mailto:sophie.staniszewska@warwick.ac.uk)

**What if there is a problem?**

This study is covered by the University of Warwick's insurance and indemnity cover. If you have an issue, please contact Jo Horsburgh (details below).

**Who should I contact if I wish to make a complaint?**

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a Senior University of Warwick official entirely independent of this study:

Jo Horsburgh  
Deputy Registrar  
Deputy Registrar's Office  
University of Warwick  
Coventry, UK, CV4 8UW.  
T: +00 44 (0) 2476 522 713 E: [J.Horsburgh@warwick.ac.uk](mailto:J.Horsburgh@warwick.ac.uk)

**Who has reviewed the study?**

This study has been reviewed and given favourable opinion by the University of Warwick's Biomedical and Scientific Research Ethics Committee (BSREC): **REGO-2014-1269 24<sup>th</sup> October 2014**. This study has also been favourably reviewed by the University of Malta Research Ethics Committee (UREC).

**Funding:**

This study is funded by the Royal College of Physicians London

*Thank you for taking the time to read this participant information leaflet*

## Appendix Q - Pre and post guideline interview consent form



**WARWICK**  
MEDICAL SCHOOL

**Pre and Post Guideline Interview Statement of Consent Form**

**Title of project:** Developing and Using Guidelines in Practice

**Name of Researcher:** Liz Avital

Please read the following and sign your agreement to participate below. You will be given a copy of this form for your information.

I confirm that I have read and understood the information sheet for the above study  
I agree to take part in the interviews  
I agree that the interviews may be audio recorded  
I understand that any information I provide is confidential  
I understand that my participation is voluntary and that I am free to withdraw from the discussion / withdraw from the study at any stage without giving any reason  
I understand that anonymised quotations may be used in publications resulting from this research  
I agree to take part in the above study

**Name of Participant:**

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Researcher:** Liz Avital

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Contact details: [Liz.Avital@rcplondon.ac.uk](mailto:Liz.Avital@rcplondon.ac.uk)

**Researcher's Supervisors:** Professor Kate Seers and Dr Sophie Staniszewska

Signature:   Date: 14.1.16

Contact details: [Kate.Seers@warwick.ac.uk](mailto:Kate.Seers@warwick.ac.uk) and [Sophie.Staniszewska@warwick.ac.uk](mailto:Sophie.Staniszewska@warwick.ac.uk)

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## **Appendix R - Pre and Post guideline development interview questions – Malta January 2016**

### **Pre guideline development interview questions**

#### **Introduction**

Asking these questions to understand how medical practice is carried out in Malta and what underpins practice

#### **What underpins practice**

- Can you tell me what evidence based health care means to you?
  - What is your view on EBHC?
  - Do you think this means the same to others in your profession / health care provision?

#### **Current practice**

- Are you able to use evidence to inform healthcare practice? (probe – pl give an example)
  - How do you use this evidence?
  - How is it received? Probe on any different reactions
- Do others in Malta use this type of evidence?
  - Can you tell me how this evidence is used?
  - Can you tell me where this evidence is used for example in what healthcare settings?
  - Can you tell me who puts this evidence into practice i.e. how is this currently done?
    - E.g. Who decides that a guideline should be used?
    - What makes it easier to use, what makes it more difficult

#### **Guidelines**

- Do you use clinical guidelines?
  - How do you use them (when are they most helpful?)
- If you were writing your own guideline, what would be the most important part?
- Where are most guidelines developed? (probe which country)
  - How do you feel about using guidelines developed outside of Malta?
- Have you ever taken part in writing a healthcare guideline?
  - Where did you get the information from?
  - How did you come to decide recommendations
- How do you think this committee will work?
- Do you have any concerns about recommendations formed by consensus?
- What do you see as the barriers to implementing guidelines?
- Can you tell me what you see as factors that help to implement guidelines?

## Post guideline development interview questions – Malta March 2016.

### Introduction

I am asking these questions to understand your experience of the guideline development.

### Experience of developing the guideline

- Can you tell me about your experience of developing a guideline through the presentation of evidence and discussion in a committee structure?
  - Did you find this helped facilitate your forming of recommendations?
- What is your view about the evidence presented i.e. did you think it was relevant, of good quality
- What would you define as non-research based evidence?
  - Did you have enough opportunity to use non research based evidence e.g. clinical experience to develop this guideline?
- Patient involvement was not really available (what are your views on this). Is this something you would wish to incorporate in the future?
  - How would you do this?
  - How do you feel about including patients in discussions about evidence?
- Can you identify any aspects that you think went particularly well and what went less well in the guideline development process?
  - What would you change / do better and why?

### Receptiveness to change

- Implementing a guideline such as this will be affected by many factors e.g. economic, social, political, cultural, do you think any of these things have had an impact on receptiveness to change in practice? (**probe this to find out more**) Do you feel one factor is more important than the others or not?
- Can you tell me if you think the departments which will need to use the guideline, are ready for the recommendations as outlined in the guideline? (If yes, what makes you think that; if no, what makes you think that.)
  - If yes or no , what can you do
- What factors can you identify which may help the acceptance of this guideline?

### Facilitation / implementation of guideline/s

- How do you think this guideline will be implemented in Mater Dei? Are there key steps?
  - Will you have a role in doing this?
  - What do you see as your role?
- Whose responsibility do you think it is to implement this guideline?
- How do you think guidelines should be put into practice across Malta?
  - How could health services work together?
- Can you tell me what the barriers to putting such evidence into practice are?
  - Is there anything that can be done to overcome these?
- Having established yourselves as a group, will this make any difference to:

- overcoming any barriers
- assisting implementation?
- What is the most important driver to putting evidence into practice?
  - How can this best be used in Malta?

**Personal: change in understanding / knowledge**

- Having gone through this process, what have you learnt about the process?
  - Critical appraisal, not to take evidence on face value?
- Does evidence based health care mean the same to you as when you started this process?
  - Have your views changed / your understanding.

## Appendix S - Statement of consent for GDG meetings to be recorded and for the information to be used as observational data.



**WARWICK**  
MEDICAL SCHOOL

**Statement of Consent for GDG Meetings**  
*(to be recorded and for the information to be used as observational data)*

**Title of project:** Developing and Using Guidelines in Practice

**Name of Researcher:** Liz Avital

Please read the following and sign your agreement to participate below. You will be given a copy of this form for your information.

I confirm that I have read and understood the information sheet for the above study and the need to record the meetings has been explained to me.  
How the recordings will be used has been explained.  
I understand that any information I provide is confidential  
I agree that the discussion may be audio recorded  
I understand that my participation is voluntary and that I can withdraw from the discussion / withdraw from the study at any stage  
I understand that anonymised quotations may be used in publications resulting from this research  
I agree for my name to be included in the full guidance document

**Name of Participant:**

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Researcher:** Liz Avital

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Contact details: [Liz.Avital@rcplondon.ac.uk](mailto:Liz.Avital@rcplondon.ac.uk)

**Researcher's Supervisors:** Professor Kate Seers and Dr Sophie Staniszewska

Signature:  Date: 14.1.16

Contact details: [Kate.Seers@warwick.ac.uk](mailto:Kate.Seers@warwick.ac.uk) and [Sophie.Staniszewska@warwick.ac.uk](mailto:Sophie.Staniszewska@warwick.ac.uk)

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## **Appendix T - Full guideline reviews and recommendations.**

### **Pharmacological and bariatric treatments.**

Reviews undertaken and compiled by the National Guideline Centre.

The guideline is copyrighted by the National Guideline Centre 2016.